(24)

No. 96-188-CFX
Status: GRANTED

Title: General Electric Company, et al., Petitioners
v.
Robert K. Joiner, et ux.

Docketed:
August 5, 1996

Court: United States Court of Appeals for the Eleventh Circuit

Counsel for petitioner: Kester,John G.

Counsel for respondent: Chesebro,Kenneth J.

Entry	Date	Note	Proceedings and Orders
1	Aug 5 1996	G	Petition for writ of certiorari filed. (Response due September 4, 1996)
2	Aug 30 1996		Waiver of right of respondents Robert K. and Karen P. Joiner to respond filed.
3	Sep 4 1996		DISTRIBUTED. September 30, 1996 (Page 127)
4	Sep 11 1996	X	Supplemental brief of petitioners General Electric Company, et al. filed.
5	Sep 25 1996	F	Response requested -- SB.
6	Oct 25 1996		Brief of respondents Robert K. and Karen P. Joiner in opposition filed.
7	Nov 5 1996		Reply brief of petitioners General Electric Company, et al. filed.
8	Nov 6 1996		REDISTRIBUTED. November 27, 1996 (Page 1)
9	Nov 27 1996		Record requested -- SB.
10	Dec 9 1996		Supplemental brief of petitioners General Electric Company, et al. (second supplement) filed.
11	Dec 16 1996		Record filed.
		*	Record proceedings U.S. Court of Appeals and U.S. District Court, Northern District of Georgia (2 boxes).
12	Dec 18 1996		REDISTRIBUTED. January 10, 1997 (Page 1)
13	Jan 13 1997		REDISTRIBUTED. January 17, 1997 (Page 19)
14	Feb 10 1997		REDISTRIBUTED. February 14, 1997 (Page 53)
15	Mar 10 1997		REDISTRIBUTED. March 14, 1997 (Page 28)
16	Mar 17 1997		Petition GRANTED. SET FOR ARGUMENT October 14, 1997. **********
18	Mar 19 1997		Order extending time to file brief of petitioner on the merits until May 30, 1997.
19	May 30 1997		Joint appendix filed.
20	May 30 1997		Brief of petitioners General Electric Company, et al. filed.
21	May 30 1997		Brief amicus curiae of United States filed.
22	May 30 1997		Brief amicus curiae of Pharmaceutical Research and Manufacturers of America filed.
23	May 30 1997		Brief amicus curiae of Dow Chemical Company filed.
24	May 30 1997		Brief amici curiae of New England Journal of Medicine and Marcia Angell filed.
25	May 30 1997		Brief amicus curiae of Chamber of Commerce of the United States of America filed.
26	May 30 1997		Brief amicus curiae of Chemical Manufacturers Association filed.
27	May 30 1997		Brief amicus curiae of American Medical Association filed.
28	May 30 1997		Brief amici curiae of Product Liability Advisory Council,

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No. 96-188-CFX

Entry	Date	Note	Proceedings and Orders
			Inc., et al. filed.
29	May 30 1997		Brief amicus curiae of Washington Legal Foundation filed.
32	May 30 1997		Brief amici curiae of Bruce Ames, et al. filed.
31	Jun 10 1997		Order extending time to file brief of respondent on the merits until July 29, 1997.
33	Jun 16 1997	G	Motion of the Acting Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
34	Jun 23 1997		Motion of the Acting Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED.
35	Jul 28 1997		Brief of respondents Robert and Karen Joiner filed.
36	Jul 29 1997	G	Motion of Ardith Cavallo for leave to file a brief as amicus curiae filed.
39	Jul 29 1997	G	Motion of Association of Trial Lawyers of America for leave to file a brief as amicus curiae filed.
41	Jul 29 1997	X	Brief amici curiae of Peter Orris, et al. filed.
37	Jul 30 1997		Brief amicus curiae of Trial Lawyers for Public Justice filed.
40	Aug 15 1997		CIRCULATED.
42	Sep 2 1997	X	Reply brief of petitioners General Electric Company, et al. filed.
43	Sep 29 1997		Motion of Ardith Cavallo for leave to file a brief as amicus curiae GRANTED.
44	Sep 29 1997		Motion of Association of Trial Lawyers of America for leave to file a brief as amicus curiae GRANTED.

Supreme Court, U.S.
FILED

No. 96 188 AUG 5 1996

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
and MONSANTO COMPANY,
Petitioners,

v.

ROBERT K. JOINER and KAREN P. JOINER,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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QUESTION PRESENTED

What is the standard of appellate review for trial court decisions excluding expert testimony under *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)?

LIST PURSUANT TO RULE 29.6

Petitioner General Electric Company is a publicly held New York corporation with no parent companies. Its subsidiaries, other than wholly owned subsidiaries and subsidiaries whose shares or debt securities are not publicly held, are General Electric Capital Corporation; General Electric Credit International, N.V.; Montgomery Ward & Company, Inc.; Credit de l'Est; Finax FS AB; Finax KK AB; GE Capital Aviation Services, Ltd.; GE Capital Mortgage Services, Inc.; GE Capital (NZ) Ltd.; GE Capital PTY Ltd.; Outlet Broadcasting, Inc.; CAMCO, Inc. (Canada); General Electric Capital Services, Inc.; GECC Financial Corporation (Hawaii); General Electric Capital Canada, Inc.; GNA Corporation; Mercur Bank (Austria); Imaging Financial Services, Inc.; Gate Finance Corporation; International GE Capital Corporation; and Service Bank GmbH.

Petitioner Westinghouse Electric Corporation is a publicly held Pennsylvania corporation with no parent companies. Its subsidiaries other than wholly owned subsidiaries are Aeg-Beteiligungagesellschaft Mbh; Aeg-Westinghouse Transport-Systems Gebb; Aws Ansaldo, Spa; C & K Software, Ltd.; Computerized and Advanced Technologies Company; Contadoras Electrice S.A.; Escorts, Ltd.; Greenfield Environmental; Hellenia Business Development; Infrared Fiber Systems Inc.; Jafco-Ltd. Partnership; Lor-West, Ltd.; Micros Systems, Inc.; Powerex, Inc.; Remotec, Inc.; Siam Toracato de Tella, Ltd.; Turbinas Y Generadores Turgenca C.A.; Vektron S.A.; W.S. Industries (India) Ltd.; Wb Bottling Corporation; and Westinghouse Surveillance Systems Limited.

Petitioner Monsanto Company is a publicly held Delaware corporation with no parent companies. It has no subsidiaries other than wholly owned subsidiaries.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

No. ———

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
and MONSANTO COMPANY,
Petitioners,

v.

ROBERT K. JOINER and KAREN P. JOINER,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

Petitioners pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Eleventh Circuit entered in this case March 27, 1996.

OPINIONS BELOW

The opinion of the District Court is reported at 864 F. Supp. 1310 and is reproduced in the Appendix at A. 34a. The opinion of the Court of Appeals is reported at 78 F.3d 524 and is reproduced at A. 1a. The orders of the Court of Appeals denying rehearing and rehearing *en banc* are unreported and are reproduced at A. 31a, 32a.

JURISDICTION

The judgment of the District Court was entered September 16, 1994. A. 69a. The judgment of the Court of Appeals was entered March 27, 1996. A. 1a. A timely petition for rehearing was denied June 11, 1996. A. 31a. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RULES INVOLVED

Rules 104, 702 and 706 of the Federal Rules of Evidence are reproduced at A. 70a.

STATEMENT

Respondents, an electrician and his wife, sued petitioners in a Georgia court claiming that his lung cancer had been "promoted" (he had smoked for eight years) by exposure to PCBs, furans and dioxins in transformers manufactured by petitioners General Electric and Westinghouse. The suit was removed to the United States District Court for the Northern District of Georgia. The District Court under Rule 702, Fed. R. Evid., excluded expert testimony proffered by respondents and granted petitioners' motion for summary judgment. The Eleventh Circuit reversed.

A. The District Court's Ruling.

The District Court held that respondents had failed to produce admissible scientific evidence that PCBs could cause respondent's small-cell lung cancer, nor that respondent had been exposed to furans or dioxins. In so holding, the court acting under Rules 104(a) and 702 of the Federal Rules of Evidence, and citing this Court's decision in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), excluded proffered testimony from two experts presented by respondents. The District Court held that evidence of causation in human beings was lacking, and that although in certain instances scientists may

use some kinds of animal studies as an indication of causation of a particular human disease, in this case such support was absent because there were only two studies, they used massive doses, and their findings were only preliminary. A. 61a. As for epidemiological data, "the studies simply do not support the experts' position that PCBs *more probably than not* promoted Joiner's lung cancer." A. 67a (emphasis in original). After reviewing in detail the methodology cited for the opinions, the District Court concluded that although there was scientific basis for opining there had been exposure to PCBs (but not furans or dioxins), the experts had presented no support in science for claiming causation:

> "The court is persuaded that the opinions of Plaintiffs' experts do not rise above 'subjective belief or unsupported speculation.'"

A. 67a, quoting *Daubert, supra,* 509 U.S. at 590.

B. The Court of Appeals' Reversal.

Splitting 2-1 and issuing three opinions, the Court of Appeals for the Eleventh Circuit reversed. The judges disagreed as to the proper standard and nature of appellate review of district court rulings under *Daubert*.

Judge Barkett, writing for the majority, held that although ordinarily district court rulings on admissibility are "reviewed for abuse of discretion," A. 4a, nevertheless "we apply a particularly stringent standard of review to the trial judge's exclusion of expert testimony." *Id.* The opinion cited as authority for this "stringent" review the Third Circuit's opinion in *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 750 (3d Cir. 1994), *cert. denied sub nom. General Elec. Co.* v. *Ingram*, 115 S. Ct. 1253 (1995). A. 5a. Using this "particularly stringent standard of review," the majority after its own examination of the opinions of two experts disagreed with the District Court's ruling, holding that "we find that the

district court improperly assessed the admissibility of the proffered scientific expert testimony . . . ." A. 2a. The majority opinion held that instead of examining whether there was support in science for each link in the reasoning leading to the experts' conclusions, the District Court should have accepted the conclusions "viewed in their entirety." A. 12. Reexamining the entire record, including materials not cited by any party in the District Court, A. 16a, the Court of Appeals held that "the testimony of plaintiffs' experts was erroneously excluded," and reversed. *Id.*

Judge Birch concurred specially, suggesting that a trial judge should "enhance the record for appellate review by appointing an expert, under Fed.R.Evid. 706, to assist the court in evaluating proffered scientific evidence," because "the need for the trial court generalist to seek expertise in discharging *Daubert* responsibilities becomes increasing[ly] evident and compelling." A. 17a.

Judge Smith, of the Federal Circuit, dissented, disagreeing with the majority's holding as to the standard of appellate review. Citing many decisions from other Circuits, he concluded that "[i]n applying the *Daubert* framework, the trial court's ruling . . . is reviewed for abuse of discretion." A. 20a (footnote omitted). "Those circuits addressing *Daubert*," he said, give "deference to the trial court's admissibility determinations." A. 20a n.1 (collecting cases). Because under *Daubert* "the trial court 'gatekeeper' has broad discretion," A. 18a, "we should not require the trier of fact to accept blindly the expert's word to fill the analytical gap between proffered 'scientific knowledge' and the expert's conclusion." *Id.* Approving "the trial court's step-by-step approach," A. 30, the dissent objected that in reversing the District Court "the majority errs by first applying the reliability prong of *Daubert* to the experts' opinions as a whole." A. 21a; see also A. 30a.

> "[S]ifting through the expert's testimony is a crucial 'gatekeeping' function that not only requires the trial court to decide which experts may testify, but also requires the trial court to decide what the experts may testify about (i.e., the trial court must separate the wheat from the chaff). . . . [A]n expert may not bombard the court with innumerable studies and then, with smoke and sleight of hand, leap to the conclusion.
>
> * * * *
>
> ". . . [I]f the trial court finds the expert testimony requires too great a leap of faith across the analytical gap, it may properly request good grounds to bridge the gap before admitting the testimony. . . . This is not too onerous a request . . . ."

A. 22a, 27a.[1] Giving "deference to the trial court's admissibility determinations," A. 20 n.1, the dissent concluded that

> "The trial court properly applied *Daubert* and did not abuse its discretion in ruling certain expert testimony inadmissible."

A. 29a-30a. Rehearing and rehearing *en banc* were denied. A. 31a, 32a.

REASONS FOR GRANTING THE WRIT

One more Circuit here has taken a position on the unavoidable question left unanswered by this Court's decision in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). That question is, what is the standard of review to be applied by the courts of appeals when reviewing a district court's exclusion of proffered expert testimony under Rule 702 of the Federal Rules of

[1] The dissent pointed out that, for example, "the trial court's ruling was not that animal studies are inadmissible *per se*, but that Mr. Joiner's general response that experts generally rely on animal studies fails to show the reliability and 'fit' of these particular animal studies," A. 25a, and "Mr. Joiner completely failed to respond to the trial court's concerns," A. 28a. The dissent also criticized the majority for reversing based on its own interpretation of portions of the record that had not been argued by the plaintiffs to the trial court. A. 22a-23a.

Evidence? Twelve Circuits now are split among three different answers, with ten Circuits according trial courts wide discretion and two holding the opposite.

The issue of standard of review is fundamental and surely will have to be resolved by this Court. It is difficult to see any reason why the time for review has not now come, particularly when the disparity of review standards among the Circuits means that judgments are being reversed in some Circuits that would be affirmed in others.

I. THE CIRCUITS ARE COMPLETELY SPLIT.

In 1994, two of these petitioners asked this Court to grant certiorari to resolve the split in the Circuits as to the proper standard of appellate review for *Daubert* rulings. Petition for Certiorari, *General Elec. Co.* v. *Ingram*, No. 94-1070, OT 1994. That petition pointed out that as of December 1994, eleven of the thirteen Circuits had addressed the question and had split in three different directions. *Id.* at 12-15. The Eleventh Circuit, the petition noted, was one of the two Circuits still to be heard from. *Id.* at 12 n.11. Now it has been, and has adopted the extreme rule theretofore followed only by the Third Circuit: that *Daubert* exclusions are to receive "a particularly stringent standard of review." A. 4a.

This Court early in 1995 denied that first petition for certiorari that asked to resolve the split over the proper *Daubert* standard of review. *General Elec. Co.* v. *Ingram*, 115 S. Ct. 1253 (1995). Since that time the Circuits have remained divided among three views. Now all except the Federal Circuit have been heard from.

To summarize the varying positions: (1) One group of courts of appeals (six of them) reverses *Daubert* rulings only if "manifestly erroneous." (2) A second group (four others) applies an "abuse of discretion" standard of review, while emphasizing the deference accorded trial court evidentiary rulings. (3) A minority of two,

illustrated by the decision here, are not deferential and instead apply a "particularly stringent standard of review," A. 4a, called by the Third Circuit a "hard look" and "more stringent review." *In re Paoli R.R. Yard PCB Litigation, supra*, 35 F.3d at 749-50. Recent representative decisions are:

A. The "Manifestly Erroneous" Standard.

Six Circuits in *Daubert* appeals follow the "manifestly erroneous" standard of review that was prescribed by this Court for rulings on admissibility of expert testimony in *Salem* v. *United States Lines Co.*, 370 U.S. 31, 35 (1962).

Seventh Circuit.—Thus the Seventh Circuit holds that under *Daubert* "we will not disturb the district court's findings unless they are manifestly erroneous." *Bradley* v. *Brown*, 42 F.3d 434, 436-37 (7th Cir. 1994).

> "In reviewing the district court's fact-specific application of the approach mandated by *Daubert*, we must apply a deferential standard of review. A 'decision to allow expert testimony is within the broad discretion of the trial judge and "is to be sustained on appeal unless manifestly erroneous."' *Bradley* v. *Brown*, 42 F.3d 434, 437 (7th Cir. 1994) (quoting *United States* v. *Daccarett*, 6 F.3d 37, 58 (2d Cir. 1993) (citation omitted), *cert. denied* [*sub nom. Creaciones Viviana Ltda.* v. *United States*], 114 S. Ct. 1294, 1295, 1538 (1994) . . . ."

Deimer v. *Cincinnati Sub-Zero Prods., Inc.*, 58 F.3d 341, 344 (7th Cir. 1995).

Second Circuit.—"A decision to allow expert testimony is within the broad discretion of the trial judge and 'is to be sustained on appeal unless manifestly erroneous.'" *United States* v. *Daccarett, supra*, 6 F.3d at 58, quoting *United States* v. *Brown*, 776 F.2d 397, 400 (2d Cir. 1985), *cert. denied*, 475 U.S. 1141 (1986). *Accord,*

McCullock v. *H.B. Fuller Co.*, 61 F.3d 1038, 1042 (2d Cir. 1995) ("left to the broad discretion of the trial judge and will be overturned only when manifestly erroneous"); *United States* v. *Amuso*, 21 F.3d 1251, 1263 (2d Cir.), *cert. denied*, 115 S. Ct. 326 (1994); *United States* v. *Locascio*, 6 F.3d 924, 936 (2d Cir. 1993), *cert. denied sub nom. Gotti* v. *United States*, 114 S. Ct. 1646 (1994).

Ninth Circuit.—"We review *de novo* the district court's interpretation of the Federal Rules of Evidence and will uphold its decision to exclude expert testimony unless it is 'manifestly erroneous.'" *Claar* v. *Burlington N.R.R.*, 29 F.3d 499, 500-01 (9th Cir. 1994), quoting *Rogers* v. *Raymark Industries, Inc.*, 922 F.2d 1426, 1429 (9th Cir. 1991). *Accord, United States* v. *Rincon*, 28 F.3d 921, 923 (9th Cir.) *cert. denied*, 115 S. Ct. 605 (1994). See also *Lust* v. *Merrell Dow Pharmaceuticals, Inc.*, 1996 U.S. App. Lexis 16690, *5 (9th Cir. 1996) ("[t]he abuse of discretion standard applies to an F.R.E. 702 ruling even though the ruling was dispositive of a motion for summary judgment").

First Circuit.—"Because gauging an expert witness's usefulness is almost always a case-specific inquiry . . . a trial judge's rulings in this sphere should be upheld 'unless manifestly erroneous.'" *United States* v. *Sepulveda*, 15 F.3d 1161, 1183 (1st Cir. 1993), quoting in part *Salem* v. *United States Lines Co., supra*, 370 U.S. at 35. See also *United States* v. *Shay*, 57 F.3d 126, 132 (1st Cir. 1995) ("district court's decision to admit or exclude expert testimony is entitled to great deference").

Fifth Circuit.—The Fifth Circuit holds that under *Daubert* "a trial court is accorded a wide berth to determine the admissibility of expert testimony." *United States* v. *14.38 Acres*, 80 F.3d 1074, 1077 (5th Cir. 1996). "A trial court's ruling regarding admissibility of expert testimony is protected by an ambit of discretion and must be sustained unless manifestly erroneous." *Rosado* v. *Deters*, 5 F.3d 119, 124 (5th Cir. 1993), quoting *Christopher-*

sen v. *Allied-Signal Corp.*, 939 F.2d 1106, 1109 (5th Cir. 1991), *cert. denied*, 503 U.S. 912 (1992). See also *Pedraza* v. *Jones*, 71 F.3d 194, 197 (5th Cir. 1995) ("district court did not abuse its discretion in refusing to consider the affidavit as expert testimony"); *Eiland* v. *Westinghouse Elec. Corp.*, 58 F.3d 176, 180 (5th Cir. 1995) ("manifestly erroneous").

Sixth Circuit.—The Sixth Circuit holds that in applying *Daubert* "A trial court 'has broad discretion in the matter of the admission or exclusion of expert evidence, and [the court's] action is to be sustained unless manifestly erroneous.'" *American & Foreign Ins. Co.* v. *General Elec. Co.*, 45 F.3d 135, 137 (6th Cir. 1995), quoting *Salem* v. *United States Lines Co., supra*, 370 U.S. at 35. *Accord, United States* v. *Bonds*, 12 F.3d 540, 554 (6th Cir. 1993) ("the trial court's actions are to be sustained 'unless manifestly erroneous'"), quoting *United States* v. *Green*, 548 F.2d 1261, 1268 (6th Cir. 1977). See also *Cook* v. *American S.S. Co.*, 53 F.3d 733, 738 (6th Cir. 1995) (referring to Rule 702 application as "a determination of relevance, which this court reviews for abuse of discretion").

B. The Deferential "Abuse of Discretion" Standard.

Without using the phrase "manifestly erroneous," four Circuits review for abuse of discretion, while emphasizing the deference to be accorded the trial judge's rulings.

Fourth Circuit.—The Fourth Circuit holds that "under the *Daubert* analysis a trial judge has a great deal of discretion in deciding whether to admit or exclude expert testimony" and a "deferential standard for reviewing evidentiary determinations" is applied. *United States* v. *Dorsey*, 45 F.3d 809, 813 (4th Cir.) *cert. denied*, 115 S. Ct. 2631 (1995). *Accord, United States* v. *Powers*, 59 F.3d 1460, 1471 (4th Cir. 1995), *cert. denied*, 116 S. Ct. 784 (1996); *United States* v. *Bynum*, 3 F.3d 769, 773 (4th Cir. 1993), *cert. denied*, 114 S. Ct. 1105 (1994).

Eighth Circuit.—The Eighth Circuit holds that district court exclusions of expert testimony under *Daubert* will be affirmed unless there was "a clear abuse of discretion." *Gier* v. *Educational Service Unit*, 66 F.3d 940, 944 (8th Cir. 1995). *Accord, Ventura* v. *Titan Sports, Inc.*, 65 F.3d 725, 735 (8th Cir. 1995), *cert. denied*, 116 S. Ct. 1268 (1996); *Watkins* v. *Schriver*, 52 F.3d 769, 771 (8th Cir. 1995) ("[t]he district court's ruling as to the exclusion of such testimony will be reversed only for an abuse of discretion").

Tenth Circuit.—The Tenth Circuit holds that a district court's admissibility rulings under *Daubert* "will be disturbed only for a clear abuse of discretion." *United States* v. *Davis*, 40 F.3d 1069 (10th Cir. 1994), *cert. denied*, 115 S. Ct. 1387 and 1806 (1995). *Accord, Kieffer* v. *Weston Land, Inc.*, 1996 U.S. App. Lexis 18191 (10th Cir. 1996); *United States* v. *Markum*, 4 F.3d 891, 895 (10th Cir. 1993).

District of Columbia Circuit.—The District of Columbia Circuit also applies an "abuse of discretion" standard in reviewing *Daubert* rulings, emphasizing that trial judges are to be allowed "broad discretion." *Joy* v. *Bell Helicopter Textron, Inc.*, 999 F.2d 549, 567 (D.C. Cir. 1993).

C. "Stringent" Non-Deferential Review.

The Eleventh and Third Circuits have adopted quite a different standard of review.

Third Circuit.—The Third Circuit uses a "heightened abuse of discretion review" that applies "a hard look at (more stringent review of) the district court's exercise of discretion" when expert testimony is excluded under *Daubert*. *In re Paoli R.R. Yard PCB Litigation, supra*, 35 F.3d at 749-50. Examining the Third Circuit's standard, Judge Wiseman wrote:

> "This creation of a new and higher standard of review appears to be without authority or precedent. It has not been followed by any other circuit as of this writing."

Wiseman, *Judging the Expert*, 55 OHIO ST. L.J. 1105, 1112 (1994).[2]

Eleventh Circuit.—But now it has been. The Eleventh Circuit in the present case, relying on the Third Circuit's *Paoli* decision, now has also adopted the "particularly stringent," A. 4a, non-deferential test that is at variance with the law in the other Circuits.

II. THE DECISION IS IN CONFLICT WITH DECISIONS OF THIS COURT.

In *Salem* v. *United States Lines Co.*, 370 U.S. 31, 35 (1962), this Court held that

> "the trial judge has broad discretion in the matter of the admission or exclusion of expert evidence, and his action is to be sustained unless manifestly erroneous."

In reiterating that standard of review, *Salem* cited and relied on language to the same effect in *Spring Co.* v. *Edgar*, 99 U.S. 645, 658 (1879) (in evidentiary rulings "the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous").

Nothing in *Daubert* or the Federal Rules of Evidence gives the slightest hint that that standard of appellate review long established by this Court was changed to narrow district courts' discretion. *Daubert*, indeed, emphasized the "gatekeeping role," 509 U.S. at 597, that trial courts are expected to perform in deciding whether

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[2] Before the present decision, another commentator observed that "*Paoli* stands almost alone—alone but for later cases in its circuit that pick up its language—in expressing the standard of review as anything but the most lenient kind of review for abuse of discretion. The non-*Paoli* cases seem to be correct." Fenner, *The Daubert Handbook: The Case, Its Essential Dilemma, and Its Progeny*, 29 CREIGHTON L. REV. 939, 1050 (1996) (footnote omitted).

opinions purportedly based on science are to be admitted into evidence, and underscored that "[t]he inquiry envisioned by Rule 702 is, we emphasize, a flexible one." *Id.* at 594. "[U]nder the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Id.* at 589.

As support for its "particularly stringent" standard of review, the Eleventh Circuit majority repeatedly assumed that this Court in *Daubert* had diminished the trial court's authority to exclude opinions invoking science. *E.g.*, A. 8a ("[k]eeping *Daubert's* lower threshold in mind"). Other courts and commentators, however, have concluded that "*Daubert* clearly requires trial judges to subject expert evidence to more penetrating pretrial scrutiny . . . ." American College of Trial Lawyers, *Standards and Procedures for Determining the Admissibility of Expert Evidence After Daubert*, 157 F.R.D. 571 (1994). See also Bernstein, *The Admissibility of Scientific Evidence After Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 15 CARDOZO L. REV. 2139 (1994) ("most federal courts are interpreting *Daubert* as giving them wide authority to restrict the scope of admissible scientific evidence in toxic tort litigation").

> "The *Daubert* Court significantly changed the standards governing the admissibility of scientific evidence by *expanding district courts' discretions to* evaluate the reliability and relevance of contested evidence."

In re Joint Eastern & Southern Dist. Asbestos Litigation, 52 F.3d 1124, 1132 (2d Cir. 1995) (emphasis supplied). See also, *e.g.*, *Wilson* v. *City of Chicago*, 6 F.3d 1233, 1238-39 (7th Cir. 1993) (*Daubert* "shifted to the trial judge the responsibility for keeping 'junk science' out of the courtroom"), *cert. denied*, 114 S. Ct. 1844 (1994); *Rosen* v. *Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996) ("the Supreme Court in *Daubert* told judges to distinguish between real and courtroom science"), *pet'n for*

cert. filed, 64 U.S.L. WEEK 3839 (U.S. June 10, 1996) (No. 95-1986).

III. THE ISSUE IS IMPORTANT.

Commentators have repeatedly pointed out that "[a]nother issue unresolved by *Daubert* concerns the standard of review of trial judges' decisions about admissibility made pursuant to *Daubert*'s new, flexible inquiry." Note, *Daubert v. Merrell Dow Pharmaceuticals: Pushing the Limits of Scientific Reliability*, 47 VAND. L. REV. 1175, 1196 (1994); see also Faigman *et al.*, *Check Your Crystal Ball at the Courthouse Door, Please*, 15 CARDOZO L. REV. 1799, 1820 (1994).

> "The standard of review for assessing lower courts' decisions regarding the admissibility of expert testimony remains unclear.
>
> * * * *
>
> "[T]he standard of review issue is not easily resolved."

Note, *Developments in the Law—Confronting the New Challenges of Scientific Evidence*, 108 HARV. L. REV. 1481, 1527, 1529 (1995). The issue not only is unresolved. It also "is important." *Mars* v. *United States*, 25 F.3d 1383, 1384 (7th Cir. 1994.)[3]

This Court amended the Federal Rules of Appellate Procedure in 1993 to require that every appellate brief "must also include for each issue a concise statement of

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[3] *Cf., e.g., Koon* v. *United States*, 116 S. Ct. 2035, 2043 (1996) ("We granted certiorari to determine the standard of review governing appeals from a district court's decision to depart from the sentencing ranges . . . ."); *Ornelas* v. *United States*, 116 S. Ct. 1657, 1661 (1996) ("We granted certiorari to resolve the conflict among the Circuits over the applicable standard of appellate review"); *Wilton* v. *Seven Falls Co.*, 115 S. Ct. 2137, 2139 (1995) ("This case asks . . . under what standard of review a court of appeals should evaluate the district court's decision . . . .").

the applicable standard of review." Fed. R. App. P. 28(a)(6). Having posed the question, this Court should not withhold the answer.[4]

CONCLUSION

For the reasons stated, certiorari should be granted.

Respectfully submitted,

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August 5, 1996

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[4] Once the proper standard of appellate review is decided, this Court need not itself reexamine the record. *Cf. Daubert*, 509 U.S. at 598 ("the case is remanded for further proceedings consistent with this opinion").

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
ELEVENTH CIRCUIT

No. 94-9131

ROBERT K. JOINER, KAREN P. JOINER,
Plaintiffs-Appellants,

v.

GENERAL ELECTRIC COMPANY, A New York Corporation; WESTINGHOUSE ELECTRIC CORPORATION, A Pennsylvania Corporation; MONSANTO COMPANY, A Delaware Corporation,

Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of Georgia

March 27, 1996

Before BIRCH and BARKETT, Circuit Judges, and SMITH,* Senior Circuit Judge.

BARKETT, Circuit Judge:

Robert Joiner ("Joiner") and his wife, Karen Joiner, brought this suit in state court on August 5, 1993, seeking

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* Honorable Edward S. Smith, Senior U.S. Circuit Judge for the Federal Circuit, sitting by designation.

damages for personal injuries from lung cancer allegedly caused by Robert Joiner's exposure to polychlorinated biphenyls ("PCBs") while working for the City of Thomasville, Georgia ("City"). Monsanto, General Electric Company, and Westinghouse Electric Corporation ("defendants") removed the action to federal district court, which excluded the testmony of the Joiners' experts and granted the defendants' motion for summary judgment, which the Joiners now appeal. Because we find that the district court improperly assessed the admissibility of the proffered scientific expert testimony and overlooked evidence establishing disputed issues of fact, we reverse the summary judgment.

Facts

Beginning in 1973, Joiner worked as an electrician in the City's Water & Light Department, a position requiring him to work with and around the City's electrical transformers. Throughout Joiner's employment, all of the City's transformers should have used as a coolant a mineral oil-based dielectric fluid which was free of PCBs.[1] However, in 1983, the City discovered PCB contamination in the dielectric fluid used in some of its transformers. From 1983 to 1993, the City conducted tests and concluded that almost one out of every five of the transformers tested presented a PCB hazard.

When a transformer was in need of repair, it was Joiner's duty to open it, drain out the dielectric fluid, bake the core of the transformer dry of dielectric fluid,[2] make repairs, refill the transformer with fresh mineral oil dielectric fluid, and then test the transformer. These repairs required that Joiner stick his hands and arms into the dielectric fluid. Joiner testified that dielectric fluid got all over him at times, that he would swallow a small amount of dielectric fluid when it splashed into his mouth, and that dielectric fluid had splashed into his eyes on several occasions.

[1] In 1978 Congress banned the production and sale of PCBs because they "present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(a)(2)(A).

[2] Joiner followed a "baking out" process during which all remaining dielectric fluid that covered the core was baked off under intense heat for several days at a time, to the point of smoking, until the transformer core was dry.

In 1991, at the age of 37, Joiner was diagnosed with lung cancer. The Joiners' theory of the case was that while Joiner's history of cigarette smoking and his family history of lung cancer may have predisposed him to developing lung cancer,[3] his exposure to PCBs and their derivatives—polychlorinated dibenzofurans ("furans") and polychlorinated dibenzodioxins ("dioxins")—served to "promote" his small cell lung cancer.[4]

Defendants moved for summary judgment on the grounds that (1) there was no admissible scientific evidence that PCBs promoted Joiner's cancer, and (2) there was no evidence that Joiner suffered significant exposure to PCBs, furans, or dioxins. The Joiners responded with the depositions and affidavits of experts who testified that PCBs alone can promote cancer and that furans and dioxins can also promote cancer, that Joiner was exposed to PCBs, furans, and dioxins, and that, in these experts' opinions, such exposure was responsible for Joiner's cancer. The district court deemed inadmissible all of the testimony presented by the Joiners' experts and granted

[3] Joiner, who had smoked cigarettes for approximately eight years, stopped smoking by 1981, ten years before his doctor diagnosed his lung cancer. *Joiner v. General Elec. Co.*, 864 F.Supp. 1310, 1312 (N.D.Ga.1994). One of the Joiners' experts testified that, notwithstanding Joiner's history of smoking, "lung cancer is extremely rare for a thirty-seven year old white male in the United States." *Id.* at 1313-14.

[4] One of the Joiners' experts explained that cancers often begin with an initiated cell which may not do harm until promoted. A "promotor" is an agent that provokes an initiated cell to turn cancerous. *Id.* at 1313.

summary judgment for the defendants.[5] In addition, although it found Joiner was exposed to PCBs, the court asserted that there was no credible evidence that Joiner had been exposed to furans and dioxins, and granted summary judgment against the Joiners on the question of exposure to furans and dioxins. *Joiner v. General Elec. Co.*, 864 F.Supp. 1310, 1326 (N.D.Ga.1994).

On appeal, the Joiners reassert the admissibility of their expert testimony to establish causation. They also contest the district court's grant of summary judgment on the issue of Joiner's exposure to furans and dioxins.

Discussion

A. *Standard of Review*

We review a grant of summary judgment de novo. *Fane v. Edenfield*, 945 F.2d 1514, 1516 (11th Cir. 1991), *aff'd*, 507 U.S. 761, 113 S.Ct. 1792, 123 L.Ed.2d 543 (1993). Summary judgment is appropriate when there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ.P. 56(c). The moving party bears the burden of showing that there is no issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325, 106 S.Ct. 2548, 2553-54, 91 L.Ed.2d 265 (1986).

A district court's ruling on the admissibility of evidence is reviewed for abuse of discretion. *Ad-Vantage Tel. Directory Consultants, Inc. v. GTE Directories Corp.*, 37 F.3d 1460, 1463 (11th Cir.1994). Because the Federal Rules of Evidence governing expert testimony display a preference for admissibility, we apply a particularly stringent standard of review to the trial judge's exclusion of expert testimony. *See, e.g., Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, ——, 113 S.Ct. 2786,

[5] The district court denied both the Joiners' and the defendants' requests for oral argument on the defendants' joint motion for summary judgment.

2794, 125 L.Ed.2d 469 (1993); *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 750 (3d Cir.1994). To the extent that the district court's ruling turns on an interpretation of a Federal Rule of Evidence, our review is plenary. *Id.* at 749.

B. *The Admissibility of Expert Testimony*

In 1923, *Frye v. United States* established a "general acceptance" test that guided district courts in determining when to admit scientific evidence. *Frye*, 293 F. 1013, 1014 (D.C.Cir.1923). This test required courts to exclude any novel scientific evidence not already grounded in a principle that had attained "general acceptance in the particular field" in which it belonged. *Id.*

In 1975, the Federal Rules of Evidence ("Rules") introduced a more liberal approach to the question of the admissibility of scientific evidence.[6] Rule 702, which specifically governs expert testimony, provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed.R.Evid. 702. Notwithstanding the Rules, most courts continued to adhere to the "general acceptance" test.

In 1993, the Supreme Court in *Daubert*, 509 U.S. at ——, 113 S.Ct. at 2793, specifically held that the Rules superseded the *Frye* "general acceptance" test. The Court made clear that the critical concerns of Rule 702 are evidentiary reliability and relevancy. *Daubert*, 509 U.S. at ——, 113 S.Ct. at 2795. Thus, an expert's bald statement that he or she is imparting "scientific knowledge" does not

[6] Rule 104(a) provides that the court shall determine "[p]reliminary questions concerning . . . the admissibility of evidence." Fed.R.Evid. 104(a).

automatically render that expert's opinion admissible. In order to best ensure relevant and reliable testimony and exclude "unsupported speculation," *Daubert* establishes a two-pronged test which requires a district court, before it may admit scientific testimony, to determine "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." *Id.* at ——, 113 S.Ct. at 2796. This "gatekeeping" role calls for the trial judge to make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid, i.e., whether it is reliable; and whether that reasoning or methodology properly can be applied to the facts in issue," i.e., whether it is relevant to the issue involved. *Id.* Proffered scientific evidence must satisfy both prongs to be admissible.

Under the first prong, evidentiary reliability, the district court must examine the reasoning or methodology underlying the expert opinion to determine whether it utilizes valid scientific methods and procedures. Trial judges must evaluate scientific processes and studies with which they may not be intimately familiar, but be careful not to cross the line between deciding whether the expert's testimony is based on "scientifically valid principles" and deciding upon the correctness of the expert's conclusions. The latter inquiry is for the jury and, therefore, judges may not implicitly factor it into their assessment of reliability.

Daubert suggests several factors to aid federal judges in evaluating whether a particular scientific theory or study is reliable: (1) its empirical testability; (2) whether the theory or study has been published or subjected to peer review; (3) whether the known or potential rate of error is acceptable; and (4) whether the method is generally accepted in the scientific community. *Id.* at ——, 113 S.Ct. at 2797-98. These factors are neither exhaustive nor applicable in every case. *See also Paoli*, 35 F.3d

at 742. Where appropriate, they serve as indicia of the reliability of the basis of an expert's testimony.

Under the second prong, relevance, the district court must determine whether the methodology or reasoning underlying the expert opinion relates to the issue at hand, i.e., whether it assists the trier of fact in understanding the evidence or a fact in issue. *Daubert*, 509 U.S. at ——, 113 S.Ct. at 2795. In this regard, the *Daubert* Court discusses the concept of "fitness," that is, "whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Id.* at ——, 113 S.Ct. at 2795-96 (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir.1985)).

In analyzing the admissibility of expert testimony, it is important for trial courts to keep in mind the separate functions of judge and jury, and the intent of *Daubert* to loosen the strictures of *Frye* and make it easier to present legitimate conflicting views of experts for the jury's consideration. *Frye* required that before an expert could testify, the proffered opinion had to be generally accepted in the pertinent field. The necessity for such broad acceptance as a condition for admissibility was eliminated by Rule 702. The admission of scientific evidence that might not yet be generally accepted in the field, however, is contingent on a trial court's finding that such evidence is indeed scientifically legitimate, and not "junk science" or mere speculation. This gatekeeping role is simply to guard the jury from considering as proof pure speculation presented in the guise of legitimate scientifically-based expert opinion. It is not intended to turn judges into jurors or surrogate scientists. Thus, the gatekeeping responsibility of the trial courts is not to weigh or choose between conflicting scientific opinions, or to analyze and study the science in question in order to reach its own scientific conclusions from the material in the field. Rather, it is to assure that an expert's opinions are based

on relevant scientific methods, processes, and data, and not on mere speculation, and that they apply to the facts in issue. Keeping *Daubert*'s lower threshold in mind, we turn to the facts of this case.

1. *Application of Daubert to this Case—Reliability*

Under the first prong of *Daubert*, the district court must identify the basis of an expert's testimony and ascertain whether the methods, procedures, and information used by the expert to reach his or her conclusion are scientifically reliable.

a. *The Basis of an Expert's Opinions*

The Joiners' chief experts were Daniel T. Teitelbaum, M.D., and Arnold Schecter, M.D., M.P.H. The record reflects that each opinion proffered by the Joiners' experts as scientific knowledge was supported by the respective experts' specialized education, years of experience, physical examination of Joiner, and familiarity with the general scientific literature in the field, as well as by reliance upon specific scientific studies relating to the carcinogenic effect of PCBs.[7] According to their curriculum vitae, each appears to have a national reputation, and the district court qualified them as experts.[8] Both experts familiarized them-

[7] Although we consider the admissibility of each expert's testimony separately, we do see similar factors supporting the admission of both experts' testimony, and for convenience we often refer to them collectively.

[8] The evidence indicated that Teitelbaum is co-founder of the American Academy of Clinical Toxicology and the American Board of Medical Toxicology. He has published more than 40 articles in his field and teaches numerous graduate level courses in occupational and environmental toxicology and the epidemiology of toxic diseases. He is also a practicing toxicologist and has repeated experience treating patients from the electrical trades. Additionally, he has lectured on medical toxicology/epidemiology for federal judges.

Schecter is professor of preventative medicine at State University of New York, Binghamton, and works full time researching the

selves with the specifics of Joiner's history and disease, and reviewed the medical literature they deemed pertinent. Teitelbaum, through his affidavit and deposition testimony, set forth the general methodology he utilized in arriving at his expert opinion:

> [I conducted] a comprehensive and traditional occupational medical assessment of Mr. Joiner. . . . As part of this assessment I interviewed and examined him . . . for several hours. In addition, I reviewed his past medical records, the data which was available about his workplace and materials with which he worked, depositions of Mr. Joiner, and others, and depositions of family members and co-workers about the nature of his work. I also considered many other documents relevant to the questions which I was asked concerning Mr. Joiner's illness and its relationship to his occupational exposures to toxic substances. . . . I utilized traditional medical assessment techniques. I also relied upon my extensive experience with workers in the electrical trades and my knowledge of the toxicology of the materials with which Mr. Joiner worked. I considered the fundamental mechanisms of toxicology and carcinogenesis as a manifestation of toxic outcome, the biology of cancer including the biology of small cell lung cancer, and the state of the art regarding the testing and evaluation of toxic substances for carcinogenic risk in humans.

Schecter also interviewed Joiner and reviewed his deposition and affidavit testimony. He conducted a review of Joiner's medical records, a videotape of the working conditions involving Joiner's repair of electrical transformers,

health effects of various toxic substances encountered in the workplace. He has published over 100 articles and abstracts subjected to peer review on the effects of workplace exposure to toxic chemicals, and has served on the editorial boards of numerous scientific and medical journals.

the results of PCB testing done on the transformers, the relevant scientific literature on the toxic effects of the substances contained in defendants' products, and all deposed expert testimony. In arriving at his opinion, Schecter claimed to have eliminated other potential causes of Joiner's lung cancer to a reasonable degree of medical certainty.

In addition, each doctor utilized numerous scientific studies and authorities. Although the district court apparently considered only four epidemiological studies and two animal studies, Teitelbaum referred to several additional studies which he utilized in forming his views. Among those not mentioned by the district court were studies by researchers Gustavsson and Hogsted, findings of the International Program on Chemical Safety ("IPCS") World Health Organization Criterion, and "a whole series of [epidemiological studies] listed in [the World Health Organization] document."

Similarly, in addition to the studies mentioned in the district court's opinion, Schecter relied, in part, upon "recent work such as that of Dr. George Lucier and colleagues at the National Institute of Health," "IARC studies, International Agency on Cancer at the World Health Organization," studies by "Dr. James Huff of the National Institute of Health," the Zober and Theiss studies from Germany, and also "Manz[']' study on European workers."

b. *Were the Methods and Procedures Underlying the Experts' Testimony Reliable?*

Likewise, the record reflects that Teitelbaum and Schecter each utilized scientifically reliable methods and procedures in gathering and assimilating all of the relevant information in forming their respective opinions. Teitlebaum stated that his methodology "has been the basis of diagnosis for hundreds of years." Schecter described his methodology as one "usually and generally followed by

physicians and scientists." Each asserted the general acceptance of the procedures they employed and defendants do not challenge these claims.

Furthermore, the extensive experience and specialized expertise of each of these experts augment the reliability of their reasoning and methodology. While this factor is most pertinent in deciding the separate question of whether the experts are qualified to testify, *see* Fed.R.Evid. 702, it also has some bearing on the determination of the reliability of the underlying reasoning or methodology. *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1125 (9th Cir.1994) (considering "expertise" to conclude that methodology underlying expert opinions satisfied *Daubert*); *Downing*, 753 F.2d at 1239 (recognizing that "[t]he qualifications and professional stature of expert witnesses . . . may also constitute circumstantial evidence of the reliability of the technique").

The assessment of reliability also involves reviewing the basis for an expert's opinion. As previously noted, when an expert relies on specific research to form an opinion, the district court must ascertain whether such research is reliable. To accomplish this, the court examines whatever evidence is proffered supporting or criticizing the research, keeping in mind the purpose of the inquiry, i.e., to exclude opinions based on mere speculation. While this inquiry cannot be made without some consideration of the quality of the research in question, the district court's focus is a narrow one and does not encompass deciding which expert's conclusions are better reasoned or more appealing. Nor should the court make independent scientific judgments on the basis of individual studies. For example, the court "rejected" the two animal studies because (1) there were only two studies, (2) which used massive doses of PCBs, (3) which represented a preliminary stage of research, and (4) which tested animals, not humans. None of these reasons is sufficient to render an expert's opinion legally unreliable. The question is whether the expert's

use of these studies to help formulate an opinion is methodologically sound. The number of studies is irrelevant to this inquiry. As the Supreme Court made clear in *Daubert*, the fact that there are a limited number of studies does not undermine the utility of those studies in assisting an expert to form an opinion. *See Daubert*, 509 U.S. at ——, 113 S.Ct. at 2797. Furthermore, it is improper to find research unreliable solely because it uses animal subjects. *See Paoli*, 35 F.3d at 781 (finding that the district court abused its discretion in excluding animal studies indicating probable link between PCBs and cancer).

Opinions of any kind are derived from individual pieces of evidence, each of which by itself might not be conclusive, but when viewed in their entirety are the building blocks of a perfectly reasonable conclusion, one reliable enough to be submitted to a jury along with the tests and criticisms cross-examinations and contrary evidence would supply. As the Supreme Court said in *Daubert*, "[t]hese conventional devices, rather than wholesale exclusion under an uncompromising "general acceptance" test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702." *Daubert*, 509 U.S. at ——, 113 S.Ct. at 2798.

In this case, the Joiners' experts discussed the studies of at least thirteen different researchers, and referred to several reports of the World Health Organization that address the question of whether PCBs cause cancer. The Joiners' experts testified that many of these studies were conducted and analyzed to test specific hypotheses about the relationship between PCBs and cancer, that many have been published in reputable scientific journals, and that they were generated and tested using the scientific method. In ruling the Joiners' expert testimony inadmissible, however, it appears that the district court first viewed each expert's opinions as based only on the six

studies discussed in her opinion [9] and then accepted defendants' criticisms of the conclusions reached in those studies, stating that "the studies simply do not support the experts' position that PCBs *more probably than not* promoted Joiner's lung cancer." *Joiner*, 864 F.Supp. at 1326. As *Daubert* makes clear, the district court may not decide whether an expert's opinions are correct, but merely whether the bases supporting the conclusions are reliable. *Daubert*, 509 U.S. at ——, 113 S.Ct. at 2797 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.").

Instead of viewing the bases of an expert's opinion as a whole to screen out mere speculation, the district court assessed only a portion of the studies relied upon by each of the Joiners' experts, and then excluded the testimony because it drew different conclusions from the research than did each of the experts. Ultimately, the court should satisfy itself as to the legal reliability of proffered expert testimony, leaving the jury to decide the correctness of competing expert opinions.

2. *Application of Daubert to this Case—Relevance*

The second prong of *Daubert* requires the court to determine whether the "testimony 'assist[s] the trier of fact to understand the evidence or to determine a fact in issue,' " by examining whether the "reasoning or methodology [underlying the testimony] can be applied to the facts in issue." *Daubert*, 509 U.S. at ——, 113 S.Ct. at 2795-96. The district court found that the experts' opin-

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[9] With one exception, the district court did not have before it any of the studies it cited in its order granting defendants summary judgment. Instead, the court apparently relied on the very brief criticisms of these studies defendants provided in their summary judgment motion. *Joiner*, 864 F.Supp. at 1325 n. 27 (noting that "[w]ith one exception, neither party has provided the court with a copy of the studies cited in the briefs [and that] the court, for the most part has had to rely on the excerpts from

ions did not "fit" the facts in the case because "the opinions [linking PCBs to cancer] are inextricably bound up with the experts' assumption that Joiner was exposed to furans and dioxins," *Joiner*, 864 F.Supp. at 1320, an assumption the court deemed unfounded. Our review of the record indicates, however, that there appears to be a genuine factual dispute as to whether PCBs alone can cause cancer, and that this issue was inappropriate for summary judgment. Although the terms "PCBs," "dioxins," and "furans" often appeared together in each expert's proffered testimony, and at times the Joiners' experts asserted that it can be assumed furans and/or dioxins were present in the City's PCB-contaminated transformer fluid, it does not necessarily follow that each expert's opinion that PCB caused Joiner's cancer was contingent upon his exposure to furans or dioxins. During his deposition, Teitelbaum testified that

> [t]here's sufficient information on PCBs. I brought the IPCS World Health Organization Criterion because it's just hot off the press, and the summary . . . indicates that as of 1987, IARC had concluded that the evidence for carcinogenicity in laboratory animals is sufficient. This is the latest piece of information, and there is no reason to doubt that, and they also concluded that PCBs are probably carcinogenic for humans.

Schecter similarly testified that "PCBs alone also cause cancer" in explaining that PCBs can initiate, as well as promote, cancer. Thus, in terms of the Joiners' claim that PCB alone can cause cancer, it becomes immaterial whether there were furans and dioxins in the fluid.

Similarly, with reference to the theory that Joiner was indeed exposed to furans and dioxins, it appears that a

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the studies that the parties have provided in their briefs"). It further appears that the court did not consider Teitelbaum's testimony as to why the studies supported his opinion that PCBs cause cancer.

genuine dispute likewise exists over whether furans and dioxins could have been present in the dielectric fluid. For example, both of the Joiners' experts testified that furans can be generated when PCBs are exposed to fires and lightning, and that furans and dioxins are often found together with PCBs. Schecter stated that "[i]t is well documented that the heating of or burning of PCBs will create both the [furans] and deadly dioxins." Teitelbaum testified that furans would inevitably result given the fact that the City's transformers had suffered fires and lightning strikes on several occasions. Teitelbaum testified during his deposition that "one simply has to look at the chemistry of the situation and what's known about PCBs manufactured in this period and assume that there was some furan present, that there may have been some dioxin present, depending on the particular fire and circumstances." *Id.* at 1321.

Defendants sought to neutralize the impact of the Joiners' evidence by establishing that neither furans nor dioxins would have been produced unless the transformer fluid exceeded a certain temperature. Defendants' expert, Dr. John F. Brown, Jr., testified that the exposure of PCBs to temperatures of 300 degrees centigrade for several days could generate furans, but that it was unlikely the City would have allowed the temperature ever to reach 300 degrees during a bake-out because of potential damage to the transformer core. Brown did not comment, however, on the temperatures that may have been reached during an accidental transformer fire which, because it is not planned by the City, does not involve intentional damage to the transformer core. Nor did the defendants provide evidence of what the temperatures in these fires might have been, or establish that the temperatures, in fact, never exceeded 300 degrees. The defendants never succeeded in rebutting the conclusions of the Joiners' experts by either establishing a threshold temperature for the conversion of furans or dioxins in a PCB solution, or presenting any direct evidence of the actual temperatures

attained during either the bake-out process or accidental fires. In contrast, Teitelbaum, when asked if he was able to "determine the temperature created from the stadium lights that were used to bake the transformer coils," replied, ["Joiner] says it was hot enough for it to smoke, and oil smokes at around 700 degrees, 800 degrees [centigrade]." In addition, while defendants' expert, Dr. Thomas O. Rouse, testified that it would be "quite unlikely" for a lightening [*sic*] strike to cause the production of furans from PCBs, *id.* at 1317 n. 12, Teitelbaum testified in his affidavit that "Mr. Joiner was directly involved in the salvage of PCB containing transformers which had been involved in a lightning strike, [and that] a lightning strike and overheating of a transformer in the presence of oxygen in the dielectric fluid, inevitably produces [furans]."

For all of the foregoing reasons, the testimony of plaintiffs' experts was erroneously excluded and summary judgment should not have been granted. Accordingly, we reversed the summary judgment and remand for proceedings consistent herewith. REVERSED and REMANDED.

BIRCH, Circuit Judge, specially concurring:

I concur in this opinion because it properly emphasizes the role of the district court as "gatekeeper." The role of the trial judge, properly following the *Daubert* mandate, is to ensure that the conclusions reached by the scientific experts have some minimal level of reliability and probative value. This determination is accomplished by establishing that the predicate principles and methodology relied upon by the experts are valid and that they can be applied to the facts at issue. The *sufficiency* of the evidence and the *weight* of the evidence, however, are beyond the scope of the *Daubert* analysis. Whether the conclusions advanced from the stated premises in fact follow and the persuasiveness of these conclusions in the

ultimate resolution of competing opinions, are questions appropriately left to the finder of fact. The trial court, nevertheless, retains its responsibility of properly instructing the jury on burden of proof and ultimately entering judgment in appropriate circumstances—all *after* the evidence has been tested through cross-examination and rebuttal evidence has been introduced.

In discharging the *Daubert* mandate, the trial court can enhance the record for appellate review by appointing an expert, under Fed.R.Evid. 706, to assist the court in evaluating proffered scientific evidence. Augmentation of the record with the testimony of a competent, independent and philosophically neutral Rule 706 expert focused upon evaluating the reliability of the proffered expert evidence will likely promote a more comprehensive and adequate ruling by the trial court. As complex scientific and technical evidence becomes more commonplace, in this ever-advancing computer age, the need for the trial court generalist to seek expertise in discharging *Daubert* responsibilities becomes increasing [*sic*] evident and compelling.

SMITH, Senior Circuit Judge, dissenting:

I respectfully dissent because the majority improperly applies *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), and does not adequately clarify the roles of the expert, the trial court and the appellate court. The following analysis is based on a few basic ideas. As a "gatekeeper," the trial court must sift through expert testimony to decide not only whether an expert may testify, but what portion of the expert's testimony is admissible. A single expert may offer several opinions to reach his ultimate conclusion, and each opinion must be admissible under *Daubert*. Further, an expert's testimony does not "assist" the

trier of fact if the expert does not explain the steps he took to reach his conclusion. We should not require the trier of fact to accept blindly the expert's word to fill the analytical gap between proffered "scientific knowledge" and the expert's conclusions. Therefore, the trial court "gatekeeper" has broad discretion to decide whether a leap of faith across the analytical gap is so great that, without further credible grounds, the testimony is inadmissible.

I. Standard of Review

The majority states that, although we review the trial court's admissibility rulings for abuse of discretion, "we apply a particularly stringent standard of review to the trial judge's exclusion of expert testimony" and "our review is plenary" over the trial court's interpretation of evidence rules. Because understanding the scope of appellate review helps define the role of the trial court, I believe we should follow other circuits and present a more precise explanation of the standard of review. *See, e.g., Cook v. American Steamship Co.*, 53 F.3d 733, 738 (6th Cir.1995) (Three standards in reviewing admissibility of expert opinion: (1) trial court's factfinding is reviewed for clear error; (2) trial court's ruling whether opinion is scientific knowledge is question of law requiring plenary review; and (3) trial court's ruling whether opinion assists the trier of fact is reviewed for abuse of discretion); *Bradley v. Brown*, 42 F.3d 434, 436-37 (7th Cir.1995) (Plenary review of whether trial court applied Daubert framework, but trial court's findings not disturbed unless manifestly erroneous.).

In applying a "particularly stringent" review, we do not change the threshold of review, but conduct a searching review of the record (i.e., take a "hard look") while maintaining the proper standard of review. *See, In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 749-50 (3d Cir.1994) (give a " 'hard look' (more stringent review)" to decide whether the trial court abused its discretion), *cert. denied*, —— U.S. ——, 115 S.Ct. 1253, 131 L.Ed.2d 134 (1995). This court already suggested such a "hard look" where it remanded a case in light of *Daubert* and instructed the trial court to make specific factfindings to facilitate appellate review. *United States v. Lee*, 25 F.3d 997, 998 (11th Cir.1994). Under this "hard look," I offer for clear guidance review terminology that is firmly established in the jurisprudence of this and other circuits. Whether the trial court properly applied Rule 702 by following the framework set forth in *Daubert* is a question of law over which this court exercises complete and independent review. *See, Peterson v. Atlanta Housing Authority*, 998 F.2d 904, 912 (11th Cir.1993) ("The district court's conclusion of law is subject to complete and independent review by this court.") (quoting, *In re Sure-Snap Corp.*, 983 F.2d 1015, 1017 (11th Cir. 1993)); *Bradley*, 42 F.3d at 436-37. I suggest the term "complete and independent" as being more precise and accurate than the ubiquitous "de novo" where the review is in fact the first one ever conducted. "De novo" carries a connotation of repetition, as in a "trial de novo" after a matter has previously been tried. To suggest that an appellate court is conducting a "new" review of the trial court's conclusions of law is less than accurate when in fact those conclusions have never before been *reviewed*. The trial court's preliminary fact-finding during a Rule 104(a) hearing to determine the admissibility of expert opinion is reviewed for clear error. *See, Elston v. Talladega County Bd. of Ed.*, 997 F.2d 1394, 1405 (11th Cir.1993) ("We review the district court's findings of fact for clear error. A finding is clearly erroneous, when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.") (quoting *Anderson v. Bessemer City*, 470 U.S. 564, 573, 105 S.Ct. 1504, 1511, 84 L.Ed.2d 518 (1985)) (internal quota-

tions omitted); *Cook*, 53 F.3d at 738. In applying the *Daubert* framework, the trial court's ruling on whether the expert opinion is (1) reliable (i.e., scientific knowledge grounded in the methods and procedures of science) and (2) relevant (i.e., "fits" the facts of the case) is reviewed for abuse of discretion.[1] *See, Hibiscus Associates*

[1] Those circuits addressing *Daubert* have shown similar deference to the trial court's admissibility determinations. *See, e.g., Pedraza v. Jones*, 71 F.3d 194, 197 (5th Cir.1995) (trial court's ruling drug addict's expert testimony inadmissible is reviewed for abuse of discretion); *Gier v. Educational Service Unit No. 16*, 66 F.3d 940, 942 (8th Cir.1995) (trial court's ruling psychologist testimony inadmissible reviewed for "clear abuse of discretion"); *Deimer v. Cincinnati Sub-Zero Products, Inc.*, 58 F.3d 341, 344 (7th Cir.1995) ("[W]e apply a deferential standard of review . . . A decision to allow expert testimony is within the broad discretion of the trial judge and is to be sustained . . . unless manifestly erroneous.") (internal quotations omitted); *Cook v. American Steamship Co.*, 53 F.3d 733, 738 (6th Cir.1995) ("[W]hether the proffered expert opinion 'will assist the trier of fact to understand the evidence or to determine a fact in issue,' is a relevancy determination and therefore one we review for abuse of discretion."); *United States v. Dorsey*, 45 F.3d 809, 814 (4th Cir.1995) ("[E]ven under the *Daubert* analysis, a trial judge has a great deal of discretion in deciding whether to admit or exclude testimony.") (citing *United States v. Bynum*, 3 F.3d 769, 773 (4th Cir.1993) ("The [*Daubert*] Court emphasized that it was prescribing a 'flexible' rule, one committed, as are most questions of admissibility of evidence, to the discretion of the district courts."), *cert. denied*, —— U.S. ——, 114 S.Ct. 1105, 127 L.Ed.2d 416 (1994)), *cert. denied*, —— U.S. ——, 115 S.Ct. 2631, 132 L.Ed.2d 871 (1995); *American & Foreign Insurance Co. v. General Electric Co.*, 45 F.3d 135, 137 (6th Cir.1995) ("A trial court has broad discretion in the matter of the admission or exclusion of expert evidence, and . . . is to be sustained unless manifestly erroneous.") (internal quotations omitted); *Bradley v. Brown*, 42 F.3d 434, 436-37 (7th Cir.1995) ("We first undertake a de novo review of whether the district court followed the framework set forth in *Daubert*[, and if so,] we will not disturb the district court's findings unless they are manifestly erroneous."); *In re Paoli*, 35 F.3d 717, 749-50 (3d Cir.1994) (a "hard look" at trial court's exercising its discretion); *United States v. Rincon*, 28 F.3d 921, 923 (9th Cir. 1994) (admissibility of expert opinion on eyewitness identification reviewed for abuse of discretion), *cert. denied*, —— U.S. ——, 115 S.Ct. 605, 130 L.Ed.2d 516 (1994); and *United States v. Muldrow*, 19 F.3d 1332, 1337 (10th Cir.1994) ("We review a trial court's admission of evidence under an abuse of discretion standard."), *cert. denied*, —— U.S. ——, 115 S.Ct. 175, 130 L.Ed.2d 110 (1994).

Ltd. v. Board of Trustees, 50 F.3d 908, 917 (11th Cir. 1995) ("A judge has broad discretion to exclude expert testimony, and his action will be upheld unless it is manifestly erroneous.").

II. Admissibility of Expert Testimony

After presenting a thorough review of the *Daubert* standard, the majority errs by first applying the reliability prong of *Daubert* to the experts' opinions as a whole, and then applying the relevancy prong. This approach treats all the experts as offering only one opinion leading to the ultimate conclusion that transformer dieletric fluids promoted Mr. Joiner's small cell lung cancer. However, each expert is actually offering several opinions leading to that ultimate conclusion. For example, the experts offer opinions that (1) furans and dioxins were present and (2) furans and dioxins promoted Mr. Joiner's cancer. Each of these assertions is a separate opinion which must meet the *Daubert* standard, regardless of whether the assertions are given by the same or different experts. As the *Paoli* court stated,

> [T]he requirement of reliability, or "good grounds," extends to each step in an expert's analysis all the way through the step that connects the work of the expert to the particular case . . . [A]ny step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible.

Paoli, 35 F.3d at 743, 745 (emphasis omitted).

The majority admonishes the trial court for not "viewing the bases of an expert's opinion as a whole." However, sifting through the expert's testimony is a crucial "gatekeeping" function that not only requires the trial court to decide which experts may testify, but also requires the trial court to decide what the experts may testify about (i.e., the trial court must separate the wheat from the chaff). Litigants may not offer all of an expert's testimony so long as they can search and find some portion that is admissible. Similarly, an expert may not bombard the court with innumerable studies and then, with blue smoke and sleight of hand, leap to the conclusion. Instead, the expert must explain how the opinion drawn from each study is acceptable under *Daubert* (i.e., how the study is methodologically grounded and "fits" the facts of the case), else the expert cannot testify about that particular study.

A. Exposure to PCBs, Furans and Dioxins

Although finding there is a genuine dispute whether Mr. Joiner was exposed to PCBs, the trial court found insufficient evidence that Mr. Joiner was exposed to furans or dioxins. The trial court dismissed Mr. Joiner's assertion that furans were created from PCBs in fire conditions because, although there was evidence of fire and other "hot" conditions, Mr. Joiner failed to show that conditions reached the requisite temperatures in this case (i.e., "fit"). *Joiner v. General Electric Co.*, 864 F.Supp. 1310, 1317-18 (N.D.Ga.1994).

The majority concludes the trial court committed reversible error by overlooking a minor passage from Dr. Teitelbaum's affidavit that provides specific evidence of "fit": (1) the transformer's were smoking which requires temperatures of 700 to 800 degrees centigrade and (2) some transformers were struck by lightning which inevitably produces furans. The majority further suggests

the trial court's ruling was erroneous because the defendants presented no evidence that the fires did not reach the requisite temperature. However, I disagree and I am not prepared to reverse the trial court on this issue because it is Mr. Joiner who has the burden of proving admissibility. *Daubert* at ——, 113 S.Ct. at 2796 n. 10 (citing *Bourjaily v. United States*, 483 U.S. 171, 175-76, 107 S.Ct. 2775, 2778-79, 97 L.Ed.2d 144 (1987)); *see also*, *Deimer*, 58 F.3d at 345 (The expert "had the responsibility to apply his analysis to the facts of this case."); *American & Foreign Insurance Co.*, 45 F.3d at 139 ("[T]he burden is on the [party seeking to admit expert testimony] to persuade this court that the testing was reliable and supported by raw data."). In making its ruling, the trial court sifted through such overwhelming evidence that it inevitably overlooked the passage from Dr. Teitelbaum's affidavit. More importantly, Mr. Joiner himself failed to disclose this passage notwithstanding his burden of proving admissibility or his knowing the case hinged on such evidence. Mr. Joiner failed to cite this or any similar passage on appeal. Indeed, this passage would have been forever lost had it not been for the diligent, searching eye of the majority. I am not prepared to place such a burden on either the trial or appellate courts. Similarly, I am not prepared to encourage litigants to inundate the courts with raw data and force the courts to process the data to determine why certain evidence is admissible. The litigants and their experts should know their evidence better than anyone—they should be their own advocates for its admission.

I would also affirm the trial court on the issue of exposure to dioxins. The trial court properly discarded treatise excerpts as inadmissible hearsay because they were not offered through expert testimony. The trial court did not abuse its discretion in discarding testimony that dioxins can be formed from Pyranol because there was no evidence that Pyranol was or may have been present in this

case (i.e., "fit"). Nor did the trial court abuse its discretion in excluding testimony that burning PCBs produces dioxins where the testimony did not reference any supporting studies (i.e., grounded in science). Finally, the trial court did not abuse its discretion in finding that expert testimony concerning a specific incident "has little probative value given the evidentiary deficits in this case." *Joiner* at 1319.

B. Causation—Promotion of Cancer

The trial court gave two alternative grounds for granting summary judgment on the issue of causation(i.e., whether Mr. Joiner's exposure to dielectric fluid promoted his cancer): (1) the experts' testimony did not "fit" because they assumed Mr. Joiner was exposed to furans and dioxins and (2) the experts did not show how the studies they relied on "fit" this case. Regarding the former ground, I am not prepared to reverse the trial court due to Mr. Joiner's failing to disclose the critical passage regarding the temperatuure of the transformers which would have provided the "fit" required to admit evidence about furans and dioxin exposure. Moreover, I would affirm the trial court on the latter ground because it did not abuse its discretion in finding the experts failed to show how the proffered studies "fit" this case.

1. Mice Studies.—The trial court found the experts' reliance on mice studies was questionable because (1) there were only two studies; (2) the studies used massive doses; and (3) the studies yielded only preliminary results. *Joiner* at 1323. The trial court excluded the studies because Mr. Joiner did not respond to these concerns, but merely "proceed[ed] as if the only issue is whether animal studies can *ever* be [proper]." *Joiner* at 1324 (emphasis added). The majority opinion apparently adopts Mr. Joiner's argument, stating that "it is improper to find research unreliable solely because it uses animal

subjects." However, this ignores the trial court's concern that the experts have not demonstrated how these mice studies "fit" this particular case.

In discussing "fit," the Supreme Court stated,

> The study of the phases of the moon . . . may provide valid scientific "knowledge" about whether a certain night was dark, and if darkness is a fact in issue, the knowledge will assist the trier of fact. However (*absent creditable grounds supporting such a link*), evidence that the moon was full on a certain night will not assist the trier of fact in determining whether an individual was unusually likely to have behaved irrationally on that night.

Daubert at ——, 113 S.Ct. at 2796 (emphasis added). In explaining the concept of "fit," the *Paoli* court stated,

> [Expert] testimony will be excluded if it is not scientific knowledge for the purposes of this case. . . . [I]n order for animal studies to be admissible to prove causation in humans, there must be good grounds to extrapolate from animals to humans, just as the methodology of the studies must constitute good grounds to reach conclusions about the animals themselves.

Paoli, 35 F.3d at 743 (emphasis in original).

The trial court's ruling was not that animal studies are inadmissible *per se*, but that Mr. Joiner's general response that experts generally rely on animal studies fails to show the reliability and "fit" of these particular animal studies. *Joiner* at 1324 n. 25. The trial court's concern is that the proffered studies (1) were on mice, not humans; (2) were of substantially higher doses of PCBs than Mr. Joiner's exposure; (3) resulted in a different form of cancer than Mr. Joiner's; (4) yielded only preliminary results and (5) were not accompanied by other studies (there were only

two studies). Because Mr. Joiner failed to address the latter two concerns, the trial court found the studies were unreliable. Regarding the other concerns about "fit", the trial court found that Mr. Joiner did not present "creditable grounds for supporting" the link between these mice studies and Mr. Joiner's cancer.[2]

It is incumbent on the proponent of scientific evidence to fill the analytical gap between a proffered study and the particular facts of the case (i.e., "fit"). *Daubert* at —— n. 10, 113 S.Ct. at 2796 n. 10 (citing *Bourjaily v. United States*, 483 U.S. 171, 175-76, 107 S.Ct. 2775, 2778-79, 97 L.Ed.2d 144 (1987)); *see also, Deimer*, 58 F.3d at 345 (The expert "had the responsibility to apply his analysis to the facts of this case."); *American & Foreign Insurance Co.*, 45 F.3d at 139 ("[T]he burden is on the [party seeking to admit expert testimony] to persuade this court that the testing was reliable and supported by raw data."). The trial court exercises its discretion to determine whether such a showing has been made, weighing several factors including the "liberal thrust" toward admitting expert evidence, the adversarial system's ability to scrutinize admitted evidence, and the powerful influence of expert opinion.[3] *Daubert* at ——,

[2] Had this law suit involved mice exposed to high doses of PCB's who developed some type of lung cancer, the "fit" would have been self-evident. However, the relationship between the studies and the facts of this case is much more tenuous.

[3] In this regard, the *Daubert* Court stated,

> Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence. . . . Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 . . . exercise more control over exports than over lay witnesses.

Daubert at ——, 113 S.Ct. at 2798.

——, 113 S.Ct. at 2794, 2798. Where no other scientific evidence is offered to fill the analytical gap, the trier of fact is required to take the expert simply on his word, placing blind faith in his expertise. However, if the trial court finds the expert testimony requires too great a leap of faith across the analytical gap, it may properly request good grounds to bridge the gap before admitting the testimony. *See, Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360-61 (6th Cir.1992) (Regarding animal studies used to show the cause of birth defects, the court found "[t]he analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue . . . is too wide. Under such circumstances, a jury should not be asked to speculate on the issue of causation."), *cert. denied*, 506 U.S. 826, 113 S.Ct. 84, 121 L.Ed.2d 47 (1992). This is not too onerous a request because the expert should certainly have reasons for drawing his conclusions from the study, else his testimony is inadmissible as the "subjective belief or unsupported speculation" that *Daubert* requires the trial court "gatekeeper" to screen out.[4] *Daubert* at ——, 113 S.Ct. at 2795.

[4] Common law precluded an expert from testifying at all about an ultimate fact in issue, relegating his role to guiding the trier of fact up to the ultimate fact without taking the final step. Although an expert may now testify to an ultimate fact, this permissiveness certainly does not permit an expert to testify solely to an ultimate fact without guiding the trier of fact to that conclusion. For example, an expert could not give a one sentence testimony. "Mr. Joiner's lung cancer was promoted by his exposure to dielectric fluid, you can take my word for it." Nor would he save his testimony by adding, "I've heard of studies that show saccharine causes cancer in laboratory animals." In order to "assist" the trier of fact, the expert must further explain his reasoning by testifying about what studies he relies on to form

Therefore, the trial court did not abuse its discretion in ruling the mice studies testimony inadmissible where Mr. Joiner completely failed to respond to the trial court's concerns.

2. *Epidemiological Studies.*—The trial court disregarded the experts' reliance on epidemiological studies because "in every case . . . the studies are either equivocal or not helpful" and "simply do not support the experts' position, that PCBs *more probably than not* promoted Joiner's lung cancer." *Joiner* at 1324, 1326 (emphasis in original). The majority reverses the trial court on this issue, alleging the trial court improperly decided whether the experts' conclusions were correct instead of limiting its analysis to whether the studies were reliable. I respectfully disagree; the trial court's concern is with "fit," not whether the experts are correct.

The *Paoli* court recognized that the distinction between focusing on an expert's methodology instead of his conclusion "has only limited practical import." *Paoli* at 746. The court explained,

> When a judge disagrees with the conclusions of an expert, it will generally be because he or she thinks there is a mistake at some step in the investigative or reasoning process of that expert. . . . [A] challenge to "fit" is very close to a challenge to the expert's ultimate conclusion about the particular case, and yet it is part of the judge's admissibility calculus under *Daubert*.

Paoli at 746. By directing attention away from the trial court's choice of terminology and toward its actual analysis, I conclude that the trial court did not abuse its discretion in ruling each study inadmissible.

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his opinion, how reliable are the studies, and how the studies relate to this particular case.

The trial court found the Bertazzi capacitor manufacturers study inadmissible because its results showed "no grounds" for linking exposure to lung cancer, and the specific excerpts relied on by the experts merely show the "plausibility," not probability, that exposure could cause cancer. *Joiner* at 1324 n. 26. These concerns alone are not dispositive because an expert may analyze a study and draw different conclusions than the study. However, an expert should have reasons for differing with the study or for finding that the study supports his conclusion notwithstanding language in the study to the contrary. Because Mr. Joiner failed to respond and provide supporting grounds, the trial court did not abuse its discretion in ruling this evidence inadmissible.

The trial court ruled the Zack & Musch Monsanto study inadmissible where the study itself stated that the results were not "statistically significant." *Joiner* at 1325. The trial court ruled the Norwegian cable manufacturers study inadmissible because it "never mentions PCBs," involves mineral oil exposure, and the study itself concludes that "[f]urther follow up . . . studies . . . are needed before any firm conclusions may be drawn." *Joiner* at 1325. The trial court also ruled the Yusho accidental toxic exposure study inadmissible because the study was a "preliminary report," the study involves persons exposed to furans and dioxins, and Mr. Joiner's own expert testified that the study "is not very convincing as the Japanese lifestyle is different . . . [it is] suggestive but not convincing." *Joiner* at 1326 (quoting Deposition of Dr. Teitelbaum). As with the Bertazzi study, the trial court did not abuse its discretion where Mr. Joiner failed to respond to the trial court's concerns and provide further grounds for relying on these studies.

III. Conclusion

The trial court properly applied *Daubert* and did not abuse its discretion in ruling certain expert testimony in-

admissible. Based on these rulings, there is insufficient evidence on the issue of causation. Therefore, I would affirm the trial court's granting summary judgment in favor of defendants. Moreover, I caution against using the majority's approach that applies each *Daubert* prong to the testimony as a whole. I would approve the trial court's step-by-step approach which properly anticipates a single expert as offering more than one opinion to support his ultimate conclusion.

APPENDIX B

[Filed June 11, 1996]

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 94-9131

ROBERT K. JOINER, KAREN P. JOINER,

Plaintiffs-Appellants,

versus

GENERAL ELECTRIC COMPANY, A New York Corporation; WESTINGHOUSE ELECTRIC CORPORATION, A Pennsylvania Corporation; MONSANTO COMPANY, A Delaware Corporation,

Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of Georgia

BEFORE: BIRCH and BARKETT, Circuit Judges, and SMITH * Senior Circuit Judge.

PER CURIAM:

The petition(s) for rehearing filed by Appellees, General Electric Co., etal, is denied.

ENTERED FOR THE COURT:

/s/ ROSEMARY BARKETT
United States Circuit Judge

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* Honorable Edward S. Smith, Senior U.S. Circuit Judge for the Federal Circuit, sitting by designation.

[Filed June 11, 1996]

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 94-9131

ROBERT K. JOINER, KAREN P. JOINER,
Plaintiffs-Appellants,

versus

GENERAL ELECTRIC COMPANY, A New York Corporation; WESTINGHOUSE ELECTRIC CORPORATION, A Pennsylvania Corporation; MONSANTO COMPANY, A Delaware Corporation,

Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of Georgia

ON PETITION(S) FOR REHEARING AND SUGGESTION(S) OF REHEARING EN BANC

BEFORE: BIRCH and BARKETT, Circuit Judges, and SMITH *, Senior Circuit Judge.

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* Honorable Edward S. Smith, Senior U.S. Circuit Judge for the Federal Circuit, sitting by designation.

PER CURIAM:

The Petition(s) for Rehearing are DENIED and no member of this panel nor other Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure; Eleventh Circuit Rule 35-5), the Suggestion(s) of Rehearing En Banc are DENIED.

ENTERED FOR THE COURT:

/s/ ROSEMARY BARKETT
UNITED STATES CIRCUIT JUDGE

APPENDIX C

[Filed Sep. 16, 1994]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

CIVIL NO. 1:92-cv-2137-ODE

ROBERT K. JOINER and KAREN P. JOINER

vs.

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
and MONSANTO COMPANY

ORDER

This diversity action is before the court on Defendants' joint motion for summary judgment, Defendants' request for oral argument on their motion for summary judgment, Plaintiffs' request for oral argument on Defendants' motion for summary judgment, and General Electric Company's motion requesting supplemental brief. Plaintiffs have filed a response in opposition to Defendants' motion for summary judgment; Plaintiffs' time to respond to the motion requesting supplemental brief has not yet expired.

Unless otherwise noted, the evidence of record shows that the following facts are not in dispute: Robert K. Joiner ("Joiner") was born on February 9, 1954. Joiner smoked cigarettes for approximately eight years. He quit in 1980 or 1981. For the last two to three years before

he quit, Joiner smoked one pack of cigarettes a day. Both of Joiner's parents smoked around Joiner while he was growing up. Joiner's father, who died when Joiner was 12, smoked throughout the time Joiner knew him. Plaintiff's mother, who died of lung cancer when Joiner was 23, smoked up to the time of her death. Joiner's maternal uncle also died of lung cancer.

Since 1973, Joiner has worked for the City of Thomasville, Georgia ("City") in the City's Water & Light Department. For the last seven to eight years, Joiner has held the title of Chief Electrician. As an incident of his job Joiner has frequently worked with and around the City's electrical transformers and voltage regulators. Joiner testified that work on electrical transformers consumed 40 to 50% of his time, while work on voltage regulators took 1% of his time.[1]

As a rule, a transformer is filled with a "dielectric fluid" that both cools and insulates the mechanism inside the transformer. This fluid typically has been a petroleum-based, flammable mineral oil. However, transformers filled with flammable mineral oil present a fire hazard when used in certain locations. Relatively early in this century a fire-resistant dielectric fluid was developed that did not contain mineral oil. Polychlorinated biphenyls ("PCBs"), a man-made chemical, were one component of the fire-resistant fluid. However, the PCB-based dielectric fluid was never widely used; "[t]he EPA has estimated that less than two-tenths of a percent (0.2%) of all utility transformers were PCB transformers. *See* 47 Fed.Reg. 17426, 17428 (1982), 'Polychlorinated Biphenyls (PCBs): Use in Electrical Equipment.'" (Defendants' Joint Memorandum in Supp. of Summ.Judg. ["Defendants' Brief"] at 6.)

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[1] For ease of reference, the court hereafter uses the terms "transformer" or "transformers" for both electrical transformers and voltage regulators.

With limited exceptions, Congress banned the production and sale of PCBs on January 1, 1978. 15 U.S.C. § 2605(e)(2)(A). Congress took this action because in its view PCBs "present an unreasonable risk of injury to health or the environment." *See* 15 U.S.C. § 2605(a).

Monsanto manufactured PCBs from 1935 to 1977.[2] General Electric Company ("GE") and Westinghouse Electric Corporation ("Westinghouse") manufacture both transformers and fire-resistant fluid. From the 1930s to the 1970s, both GE and Westinghouse marketed fire-resistant fluid containing PCBs; GE's product carried the trade name "Pyranol," while Westinghouse's carried the trade name "Inerteen."

Throughout the time of Plaintiff's employment, all of the City's transformers have used mineral oil-based dielectric fluid, which should be free of PCBs. However, beginning in 1983, the City discovered, via systematic testing, that the dielectric fluid in some of its transformers was contaminated with PCBs.[3] From 1983 to 1993, the City tested approximately 2,668 of its transformers.[4] Approximately half of the transformers tested showed PCB contamination. However, the EPA considers any

[2] Plaintiffs assert, without contradiction from Defendants, that after 1935 Monsanto was the sole manufacturer of PCBs in the United States.

[3] Defendants assert that

> [a]lthough there are several methods by which this contamination could have occurred, including through maintenance and repair, the source of the PCB contamination is not an issue in this motion for summary judgment, which is limited to the causal connection, if any, between PCBs and Mr. Joiner's small cell lung cancer.

(Defendants' Brief at 6 n. 7.)

[4] The court reached this figure using the computer printout that is attached to the affidavit of Mark Homyk, the City's Director of Engineering and Electrical Operations. Neither side has cited to the court evidence regarding the total number of transformers the City possesses.

transformer that contains PCBs at a level less than 50 ppm to be a "non-PCB transformer" which is not subject to regulation. 40 C.F.R. § 761.3 (1993). Of all the transformers tested, about 2.5% contained levels of PCBs above 500 parts per million ("ppm"), while about 16.7% contained levels above 50 ppm.[5] Thus, almost one out of every five (i.e., 19.2%) of the transformers the City tested presented a PCB hazard.

> When a transformer was in need of repair, it was . . . Joiner's duty to open it up, drain out the dielectric fluid, bake the core of the transformer dry of dielectric fluid, make repairs which were within his skills, refill the transformer with fresh mineral oil dielectric fluid, and then test the transformer for proper operation. The process of repairing transformers required that . . . Joiner stick his hands and arms into the dielectric fluid to perform necessary repairs and disassembles. The next step required the separation of the core of the transformer from the tank so that it could be dried, cleaned, inspected and repaired. This step also exposed . . . Joiner to the dielectric fluid. . . .
>
> In order to dry the transformer, a process called "baking out" was followed. During the baking out process, the dielectric fluid which covered the core after it was untanked was baked off the transformers, for several days at a time, with the intense heat of football field lights, to the point of smoking, until the core was dry. Baking out is a recommended maintenance practice.

(Plaintiffs' Brief in Opp. to Defendants' Motion for Summ.Judg. ["Plaintiffs' Brief"] at 20-21.)[6]

[5] One of the transfomers tested (which neither GE nor Westinghouse had manufactured) contained PCBs at the level of 1,880 ppm. This was the highest reported level for any of the City's tested transformers.

[6] During his deposition, Joiner testified that dielectric fluid got all over him at times. (Joiner Dep. at 95.) He also testified that

In 1991, at the age of 37, Joiner was diagnosed with lung cancer. Defendants assert that Joiner's ailment is of a variety known as "small cell lung cancer." In response, Plaintiffs argue that "a description of the particular cancer as being 'small cell' cannot be admitted as lung cancer cannot readily be catalogued this simply." (Plaintiffs' Response to Defendants' Statement of Material Facts, etc., ¶ 8.) Plaintiffs offer no evidence to support their objection. Moreover, through the affidavit of Joanne Beauvoir Brown, counsel for Monsanto Company ("Monsanto"), Defendants have submitted a pathology report that contains the following diagnosis:

> We performed routine H & E staining on one slide and immunohistochemical staining for cytokeratin, T-cell antigen (UCHL) and B-cell antigen (L26) on the others. The routine H & E stained slide shows a poorly differentiated malignant tumor present within soft tissue. There is extensive crush artifact that makes interpretation difficult. However, the tumor is composed of small cells with dispersed nuclear chromatin pattern and scant cytoplasm. The cells infiltrate between adipose tissue and lack cohesion. The differential diagnosis on the routine stain is between a small cell carcinoma and a lymphoblastic lymphoma. Our imunohistochemical stains show weak staining in the cells for cytokeratin and negative staining for the lymphoid markers. These findings confirm the epithelial nature of the tumor and support a diagnosis of small cell carcinoma.

(Brown Aff., Ex. A.) Given this evidence, the court finds that there is no genuine dispute over the fact that Joiner suffers from small cell lung cancer.

Dr. Arthur L. Frank (M.D.) is one of Plaintiffs' experts. His affidavit provides in part as follows:

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he had swallowed a small amount of dielectric fluid when it splashed into his mouth, *id.* at 102, and that dielectric fluid had splashed into his eyes on several occasions, *id.* at 108.

> Lung cancer, like other cancers, begins with an initiated cell. The initiator can be any number of things including, but not limited to, tobacco smoke. An initiated cell does no harm by itself until it is promoted. An initiated cell can survive for a number of years without any harmful effects on the body. There are a wide variety of known and suspected promoters of lung cancer.
>
> Epidemiology studies and statistics, and my own personal observations and experience, indicate that lung cancer is extremely rare for a thirty seven year old white male in the United States. This is true even for persons with a history of tobacco use. Lung cancer, as a general rule, is not seen until much later in life.
>
> . . . .
>
> . . . It is more likely than not, given Mr. Joiner's limited tobacco use, and also considering his second hand tobacco smoke exposure, and given his age at the onset of lung cancer, 37 years, that tobacco smoke served only as the initiator of the cancer and that some other agent served as the promoter of the initiated cells. It was the promotion of the initiated cells which caused Mr. Joiner to be harmed.

(Frank Aff., ¶¶ 5, 6, 8.) Plaintiffs' theory, as stated by their experts, is that PCBs and their derivatives—polychlorinated dibenzofurans ("PCDFs" or "furans") and polychlorinated dibenzodioxins ("PCDDs" or "dioxins") —served as promoters of Joiner's lung cancer.

On August 5, 1992, Plaintiffs filed this action in the State Court of Fulton County, Georgia. Defendants timely removed the action to this court. The complaint contains the following counts:

> Count One—Strict liability against GE and Westinghouse.
>
> Count Two—Negligence against GE and Westinghouse.

Count Three—Fraud against GE and Westinghouse.

Count Four—Strict liability against Monsanto.

Count Five—Negligence against Monsanto.

Count Six—Loss of consortium against all Defendants.

Count Seven—Punitive damages against all Defendants.

On August 24, 1993, Plaintiffs, with leave of court, amended their complaint. This amendment made Count Seven a claim of battery against all Defendants, while the punitive damages claim became Count Eight.

Summary judgment is appropriate only "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). In ruling on Defendants' motion, the court must view the evidence in a light most favorable to Plaintiffs. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970). To prevail on their motion for summary judgment, Defendants must show that the evidence is insufficient to establish an essential element of Plaintiffs' case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). If Defendants make a sufficient showing, then Plaintiffs "must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting Fed.R. Civ.P. 56(e)). If the evidence supporting Plaintiffs' claims is insufficient for a jury to return a verdict for Plaintiffs, or is merely colorable or not significantly probative, then Defendants are entitled to summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). If, however, reasonable minds could differ

as to the import of the evidence, and a reasonable interpretation of the evidence could lead to a verdict for Plaintiffs, then summary judgment is inappropriate. *Id.* at 251-52.

Defendants offer two grounds in support of their motion for summary judgment: One ground is that Joiner did not suffer significant exposure to PCBs, furans, or dioxins. The other ground is that "plaintiffs . . . cannot present credible, admissible scientific evidence that . . . small cell lung cancer in humans can be caused or promoted by PCBs." (Defendants' Brief at 10.) In light of these arguments, the court first must determine if there is a genuine dispute over the allegedly-carcinogenic substances to which Plaintiffs assert Joiner was exposed. Second, the court must determine if Defendants are correct in arguing that Plaintiffs cannot show a link between PCBs and small cell lung cancer.

EXPOSURE

Defendants first argue that Joiner was not exposed to significant amounts of PCBs and, even if he was, that he did not receive a harmful dose. Defendants offer the following explanation of the difference between the terms "exposure" and "dose":

> In toxicology, "dose" or "intake" indicates the amount of chemical that is actually absorbed into the body. "Exposure" means the eligibility or potential to have contact with a particular chemical. The fact that one may have been potentially exposed to a chemical such as PCBs does not prove that one has absorbed a dose of PCBs.

(Defendants' Brief at 4 n. 4.) Defendants make several arguments in support of the exposure/dose ground of their motion for summary judgment:

1. Joiner's exposure to transformers that presented a PCB hazard was episodic, not daily, from 1973 to sometime between 1983 and 1987.

2. All of the transformers the City purchased were filled with mineral oil-based dielectric fluid.

3. Only one out of five of the City's transformers presented a PCB hazard.

4. Plaintiffs' test of the PCB content of Joiner's adipose tissue revealed a PCB level of 0.3 ppm, while Plaintiffs' experts testified that the average PCB level in North America for persons without any occupational exposure to PCBs is 0.4 or 0.5 ppm.[7]

The evidence Defendants rely upon to argue that Joiner was not exposed to PCBs can as easily be viewed as follows: Joiner has worked for the City for many years; at least 512 of the City's transformers (i.e., 19.2% of 2668 transformers tested) presented a PCB hazard; and disassembly of transformers was a routine part of Joiner's work. Given this view of the facts, the court finds that Defendants' first three arguments do nothing more than show the need for a jury to weigh and then choose one of the conflicting interpretations that each side advances for the same evidence.

Further, Plaintiffs accurately note two problems with Defendants' fourth argument. First, Plaintiffs point out that while the results of a Joiner's adipose tissue test do not show a higher than normal ppm level, the results do, in fact, show that Joiner has been exposed to PCBs. Second, through the affidavit of Dr. Arnold Schecter (M.D.),

[7] Neither party has cited to the court evidence regarding the definition of "adipose tissue." A commonly-used dictionary defines the term as "animal tissue in which fat is stored, consisting of connective tissue with the cells distended by droplets of fat and constituting the fat of meat." *Webster's Third New International Dictionary* 26 (Merriam-Webster 1986). The court takes judicial notice of this definition. *See* Fed.R.Evid. 201(b), (c).

one of their experts, Plaintiffs contend that the existence of Joiner's cancer, the treatment of the cancer, and passage of time together make unreliable the low level that the adipose tissue test shows:

> No study has been documented that examines subjects who have experienced weight loss associated with cancer, chemotherapy associated with cancer, and radiation therapy associated with cancer, as well as been subjected to excessive PCB, dioxin or dibenzofuran exposure. As a result, there is no control group to which Robert Joiner can be compared. . . .
>
> Adipose levels which are low do not mean that higher levels did not exist at earlier times. This is because PCBs are metabolized and excreted from the body over time.

(Schecter Aff., ¶ 22.) Defendants attack Dr. Schecter's affidavit as inconsistent with his deposition and also offer the testimony of their own expert in rebuttal to Dr. Schecter's position.[8] In doing this, Defendants succeed

[8] In this context, a "congener" is "a chemical substance related to another (as a derivative or an element in the same group of the periodic table as another element)." *Webster's Third New International Dictionary* 478 (Merriam-Webster 1986). The court judicially notices this definition. *See* footnote 7, *supra*. Dr. Schecter responded in the affirmative when asked whether the congeners of high-chlorinated PCBs remain at a relatively constant level for several years in human adipose tissue. (Schecter Dep. at 107.) At another point, Dr. Schecter testified that "I do have an opinion that the metabolism is going to be altered and there are—obviously will be transfer and changes. *How they will be reflected in these tests, I don't know.*" *Id.* at 30-31 (emphasis added). Dr. John F. Brown, Jr. (Ph. D), one of Defendants' experts, testified that

> the level of PCB's and PCDF's were both within the lower part of the range normally involved in environmentally exposed populations, that there were no obvious abnormalities that might have resulted from accelerated clearance, that the homologue distribution in the PCB's were again very similar to what we and many others have seen in background populations.

(Brown Dep. at 87.)

only in showing a dispute in the evidence, not the absence of evidence.

In view of the foregoing discussion, the court finds that a geninue dispute exists over whether Joiner was exposed to PCBs. Thus, Defendants are not entitled to summary judgment on this issue. It remains to be seen if there is a genuine dispute on the furans/dioxins issues.

Defendants make the following arguments to show the absence of evidence that furans and/or dioxins were in the PCBs to which Joiner allegedly was exposed:

> (1) [T]here is no analytical test data that any of Thomasville's transformers or voltage regulators ever contained any PCDFs or PCDDs (Schecter Depo., at 86); (2) plaintiffs had Mr. Joiner's adipose tissue analyzed for the presence of PCDFs and PCDDs, and demonstrated that his body levels for both were virtually nondetectable and well below background levels (Robertson Depo., Exhibit 7);[9] (3) there is no scientific evidence that PCDDs are created from PCBs under any conditions (Rouse Depo., at 86);[10] (4) Dr. Schecter does not know whether the formation of PCDFs from PCBs would be inhibited or reduced by the dilution of PCBs in mineral oil (Schecter Depo., at 133-134); and (5) Dr. Schecter does not know the temperature or other conditions necessary to generate PCDFs from PCBs (Schecter Depo., at 133).

(Defendants' Brief at 24.) The court first addresses the furans issue.

Defendants' first argument is correct. Plaintiffs can point to no test data that shows the existence of furans or dioxins in any of the City's transformers.

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[9] Dr. Larry Robertson (Ph.D.) is one of Plaintiffs' experts.

[10] Dr. Thomas O. Rouse (Ph.D.) is one of Defendants' experts.

Defendants' second argument is also correct. Plaintiffs do not dispute that the adipose tissue test showed negligible levels of furans and dioxins. Even though they arranged to have the test conducted, Plaintiffs now contend that the test results should be disregarded because the testing agency used an inappropriate methodology and there is no control group against which to compare the results. (Plaintiffs Brief at 25-26.) Dr. Schecter supports this contention. (Schecter Aff., ¶ 22.)[11]

Defendants' fourth argument is substantially accurate. During his deposition, Dr. Schecter testified that he did not recall any studies which showed that mineral oil inhibits or reduces the formation of furans from PCBs. (Schecter Dep. at 133.) Both Doctors Brown and Rouse testified that the production of furans from PCBs would be inhibited if the PCBs were diluted in mineral oil. (Brown Dep. at 24-25, 31; Rouse Dep. at 40-41.)

Defendants' fifth argument is not totally accurate. Dr. Schecter testified that in temperatures between 200 and 600 degrees centigrade "you get a yield of PCBs being empirically converted to a reasonabl[y] larger yield of

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[11] Dr. Schecter's affidavit reads in part as follows:

> I discussed the techniques followed by Triangle Laboratories with the chemist who conducted the tests. I believe mistakes were made. I do not believe that a reasonable scientist could use these results to compare Robert Joiner to other humans. The results show no detectable levels of PCDDs in Robert Joiner's blood for congeners which are known to exist at detectable levels in adults in North America. This casts considerable doubt on the methodology followed and further convinces me that no reasonable and experienced dioxin medical scientist would rely on them.

(Schecter Aff., ¶ 22.) In their reply, Defendants assert that "it is hardly appropriate scientific methodology to obtain adipose tissue measurements, then claim they are unreliable because they do not show what you hoped they would." (Defendants' Joint Mem. in Reply to Plaintiffs' Brief in Opp. to Defendants' Motion for Summ. Judg. ["Defendants' Reply"] at 3 n. 4.)

dibenzofurans." (Schecter Dep. at 115.) However, Dr. Schecter declined to state, even after repeated questioning, what the minimum temperature is for the formation of furans from PCBs. *See id.* at 115-18.[12]

The court finds Defendants have made a satisfactory showing that there is insufficient evidence to establish that Joiner was exposed to furans or dioxins. Plaintiffs thus "must come forward with 'specific facts showing that there is a genuine issue for trial.' " *Matsushita Elec. Indus. Co.*, 457 U.S. at 587 (quoting Fed.R.Civ.P. 56(e)).

Plaintiffs first argue that PCBs are always contaminated with furans. In support of this position, Plaintiffs offer a number of citations to learned treatises. (*See* Plaintiffs' Brief at 14-15.)[13] This purported evidence is unavailing. Evidence offered in connection with a motion for sum-

[12] By seeking to establish the minimum temperature for the conversion of furans from PCBs. Defendants obviously aim to show that neither transformer fires nor the baking out process would have generated a temperature high enough for such conversion. Dr. Brown testified that furans could be generated from PCBs if the PCBs were exposed to temperatures of 300 degrees centigrade for several days. (Brown Dep. at 38.) Defendants do not cite direct evidence regarding the temperatures that were reached during a transformer fire or the baking out process. Instead, they attempt to show that no one would have sought to reach furan-generating temperatures during the baking out process, because to do so would have damaged the paper insulation contained in the transformer core. (Rouse Dep. at 85 ["(I)t seems . . . very unlikely that paper would survive temperatures of 300 degrees without charring, blacking. . . ."].) As for lightning, Dr. Rouse testified that it would be "quite unlikely" for a lightning strike to cause the production of furans from PCBs. *Id.* at 84.

[13] For example, Plaintiffs quote an article from a medical journal for the proposition that " '[a]ll commercially produced PCBs are contaminated with the polychlorinated dibenzofurans.' " (Plaintiffs' Response at 15 [quoting Gideon Letz, *The Toxicology of Polychlorinated Biphenyls—An Overview for Clinicians*, 138 West J. Med. 534, 540 (1983)].) Plaintiffs have not provided the court a copy of this article.

mary judgment, whether contained in an affidavit or otherwise, must be admissible. Rule 56(e) ("Supporting and opposing affidavits shall be made on personal knowledge [and] *shall set forth such facts as would be admissible in evidence. . . .*") (emphasis added); *Aguilera v. Cook County Police & Corrections Merit Bd.*, 760 F.2d 844, 849 (7th Cir.) ("Sworn testimony is not the only basis on which summary judgment may be granted; 'the court may consider any material that would be admissible or usable at trial.' 10A Wright, Miller & Kane, Federal Practice and Procedure § 2721, at p. 40 (2d ed. 1983) (footnote omitted)."), *cert. denied*, 474 U.S. 907 (1985). The learned treatises, being hearsay, are inadmissible.[14]

Plaintiffs next assert that furans are created from PCBs in fire conditions. This argument ties in with Defendants' efforts to establish the minimum temperature at which furans are converted form [*sic*] PCBs. The argument is relevant because Joiner testified that some of the transformers he worked on required service because they had caught on fire. Moreover, as noted earlier the City used stadium lights to "bake out" transformer cores.

Plaintiffs again cite to learned treaties to show that furans can be generated when PCBs are exposed to fire. However, Plaintiffs also cite Dr. Schecter's affidavit to support their argument:

> PCBs are very similar chemicals to dioxins and dibenzofurans, which are also very toxic synthetic chemicals. They are frequently found together. . . . We learned from Christopher Rappe and H.R. Buser, European chemists, that when PCBs burn in the presence of oxygen they form much of the more toxic

[14] It is true that learned treatises are saved from exclusion as hearsay when an expert relies on them in giving his opinion. Fed.R.Evid. 803(18), yet Plaintiffs have not cited to the court expert testimony that supports the expansive proposition they advance.

> dibenzofurans and some dioxins. When the chlorinated benzenes sometime found in PCB transformer fluid burn, they yield higher amounts of dioxins and lesser amounts of dibenzofurans. Dibenzofurans are usually found in PCB transformer fluids, as reported in numerous reports and at many scientific meetings. In the Binghamton, New York transformer fire, we found PCBs, dibenzofurans and dioxins in the soot and in the air after the fire.

(Schecter Aff., ¶ 19.)

The court is troubled by the fact that Dr. Schecter is a medical doctor, not a chemist like Doctors Rouse and Brown. *Cf.* Fed.R.Evid. 702 (A person qualifies as an expert "by knowledge, skill, experience, training, or education."). Nevertheless, even accepting Dr. Schecter's testimony that furans can be produced from PCBs at 200 degrees centigrade, Plaintiffs have not carried their burden of showing a genuine dispute on the furans issue.

It is not enough for Plaintiffs to show that furans can be created when PCBs are exposed to a certain temperature. It is also Plaintiffs' task to link that evidence to the facts of this case, i.e., to show some credible evidence that the City's transformers were exposed to a temperature hot enough to generate furans. Plaintiffs' argument in this regard is as follows:

> When the transformers came into the shop, they were often still smoking from having been on fire. (Robert Joiner Deposition at 115-116). The dielectric fluid which had been on fire remained heated, smoky, and steamy. . . . During the bake out process, "[s]moke would boil off them and in the same area where we worked." (Robert Joiner Deposition at 113). . . . On occasion, the metal parts of the transformers would turn red hot.

(Plaintiffs' Brief at 22-23.) Essentially, Plaintiffs argue that because the transformers got hot, there is a genuine

dispute on the furans issue. The court disagrees; at a minimum, Plaintiffs must produce expert testimony to show that the transformer fires or baking out process produced temperatures of at least 200 degrees centigrade. Plaintiffs have not cited such evidence to the court. The court thus finds that the evidence Plaintiffs have produced is insufficient to allow a jury to determine that Joiner was exposed to furans. *See Anderson*, 477 U.S. at 249 (if evidence supporting non-moving party's claims is insufficient for a jury to return a verdict for him, or is merely colorable or not significantly probative, then moving party is entitled to summary judgment).

Defendants' straightforward argument on the dioxins issue is based on the following testimony by Doctors Rouse and Brown:

> Q Can [PCDDs] be created . . . in a PCB contaminated transformer, meaning for my question, less than 1000 parts per million in mineral oil as a result of any foreseeable lightning strikes, fire, excessive heat, electrical arcing?
>
> A There is no evidence that PCDDs are created from PCBs under any conditions.

(Rouse Dep. at 86.)

> Q Do you believe there is any association between PCDD and PCB; that is, a PCB in any fashion —sunlight, aging, fire—anything that can convert PCB's to PCDD's?
>
> A I do not believe so.

(Brown Dep. at 24.)

The court finds that this is sufficient evidence to warrant summary judgment in Defendants' favor on the dioxins issue. Thus, the burden shifts to Plaintiffs to show a genuine dispute on the existence of dioxins in the dielectric fluid at issue.

Plaintiffs' response to Defendants' argument is as follows:

> "Polychlorinated dibenzo-p-dioxins are not found in commercial PCBs. However, when PCBs are mixed with other chlorinated compounds, such as the chlorobenzenes used in transformers, PCDDs can be found in the case of accidental fires and during incineration." Even Defendants' expert, Dr. Brown, affirmed that PCDD could be formed from askarel products such as Pyranol.[15] (Brown Deposition at 20) It is well documented that the heating or burning of PCBs will create both the dibenzofurans and deadly dioxins. (Schecter Affidavit ¶ 16.)
>
> In a February 5, 1981 incident in Binghamton, N.Y., with which Dr. Arnold Schecter, is personally familiar, a PCB transformer caught on fire. Thirteen years later, the building remains uninhabitable because of contamination by PCDFs and PCDDs formed in the fire. (Schecter Affidavit ¶ 16) Robert Joiner dealt with transformer fires on a regular basis.

(Plaintiffs' Brief at 16 [footnote omitted].)

Plaintiffs' argument is unavailing. The portion of the argument in quotation marks comes from a learned treatise and is thus hearsay for the reasons discussed earlier. While Dr. Brown did testify that dioxins can be generated from Pyranol, Plaintiffs have produced no evidence to show that Pyranol is the source of the PCB contamination in the City's transformers.[16] Contrary to Plaintiffs' argu-

[15] The court judicially notices that an askarel is "a synthetic electrically insulating fluid that is noncombustible." *Webster's Third New International Dictionary* 128 (Merriam-Webster 1986). *See* footnote 7, *supra*.

[16] Dr. Brown's testimony reads as follows:

> Q. What about PCDD's from other ingredients in commercial askarels; for example, Pyranol has—trichlorobenzyne is a major constituent, about 40 percent of that; correct?
>
> A. Yes.

[Continued]

ment, the cited portion of Schecter's affidavit contains no citations to any studies which show that dioxins can be generated from PCBs. Dr. Schecter's conclusory, sensationalistic description of his experience with a transformer fire in New York has little probative value given the evidentiary deficits in this case. Finally, even if Plaintiffs could show that dioxins are generated from PCBs in a high temperature situation, they still have failed (as the foregoing discussion shows) to demonstrate a genuine dispute that the transformers at issue here reached the requisite high temperature. For all these reasons, the court finds that Defendants are entitled to summary judgment on the issue of whether Joiner was exposed to dioxins.

PCB/SMALL CELL LUNG CANCER LINK

Defendants argue that the record contains no admissible evidence that Plaintiff Joiner's small cell lung cancer was caused by his exposure to PCB's. "When medical causation is at issue, plaintiffs must prove causation to a 'reasonable degree of medical certainty.'" *Wells v. Ortho Pharmaceutical Corp.*, 615 F.Supp. 262, 295 (N.D. Ga. 1985) (Shoob, J.) (quoting *Parrott v. Chatham County Hosp. Auth.*, 145 Ga.App. 113, 115 (1978)), *aff'd, modified in part, and remanded*, 788 F.2d 741 (11th Cir); *cert. denied*, 479 U.S. 950 (1986.) Given this standard, resolution of Defendants' motion for summary judgment largely depends on the admissibility of certain expert testimony that Plaintiffs have presented. Since the standards governing the admission of expert scientific testimony have been the subject of a recent Su-

[16] [Continued]

> Q. Can PCDD be formed from the askarel mixture which included trichlorobenzynes through fire, aging, sunlight, or any other action of which you are aware of?
>
> A. Yes. I am aware that there have been scientific reports of the conversion of chlorobenzynes to trace quantities of PCDD's at high temperatures.
>
> (Brown Dep. at 24.)

preme Court case, it is helpful for the court at this point to review briefly how those standards have evolved.

In *Frye v. United States*, 293 F. 1013 (D.C. Cir.1923), the D.C. Circuit rejected the results of a primitive lie detector test with the following comment: "[W]hile courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs." *Id.*, 293 F. at 1014. Until 1993, the "general acceptance" test that *Frye* announced was "the dominant standard for determining the admissibility of novel scientific evidence at trial." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. ——, ——, 125 L.Ed.2d 469, 478 (1993). In *Daubert*, the Supreme Court discarded the *Frye* standard on the ground that the Federal Rules of Evidence had supplanted it. *Daubert*, 125 L.Ed.2d at 479.[17] Specifically, the Supreme Court held that Rule 702 of the Federal Rules of Evidence, not the general acceptance test, provides the governing standard when a litigant offers expert scientific testimony.

Rule 702 provides in part as follows: "If scientific . . . knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." The Supreme Court amplified on Rule 702's requirements as follows:

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[17] In *United States v. Hope*, 714 F.2d 1084 (11th Cir.1983), a panel of the Eleventh Circuit noted the argument that the Federal Rules of Evidence had replaced the *Frye* standard, but found it unnecessary to resolve the issue. *Id.*, 714 F.2d at 1087 n. 3. In *United States v. Piccinonna*, 885 F.2d 1529 (11th Cir.1989), the Eleventh Circuit *en banc* appeared to endorse the use of *both* Rule 702 and the *Frye* standard. *Id.* 885 F.2d at 1531. *Daubert* has now settled the issue.

> Faced with a proffer of expert scientific testimony . . ., the trial judge must determine at the outset, pursuant to Rule 104(a) whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

Daubert, 125 L.Ed.2d at 482 (footnote omitted).

In one of the footnotes omitted from the foregoing passage, the Supreme Court quotes Rule 104(a). Rule 104(a) commits to the trial court the resolution of preliminary questions regarding the admissibility of evidence. The rule states that in making this determination the court "is not bound by the rules of evidence except those with respect to privileges." The standard that guides the court as it weighs the admissibility of evidence is the "preponderance of proof." *Daubert*, 125 L.Ed.2d at 482 n. 10 (citing *Bourjaily v. United States*, 483 U.S. 171, 175-76 (1987)).

Defendants make a number of arguments to show that Plaintiffs cannot demonstrate a link between PCB exposure and small cell lung cancer. The strongest of these arguments is that the opinions of Plaintiffs' experts do not fit the facts in this case because the opinions are inextricably bound up with the experts' assumption that Joiner was exposed to furans and dioxins.

As discussed above, the admissibility analysis under Rule 702 has two prongs. The second prong requires that the proffered evidence "assist the trier of fact to understand or determine a fact in issue." *Daubert*, 125 L.Ed.2d at 481. To illustrate this point, the Supreme Court commented with approval on Judge Edward R. Becker's

opinion in *United States v. Downing*, 753 F.2d 1224 (3d Cir.1985):

> The consideration has been aptly described by Judge Becker as one of "fit." [*Downing*, 753 F.2d at 1242.] "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . The study of the phases of the moon, for example, may provide valid scientific "knowledge" about whether a certain night was dark, and if darkness is a fact in issue, the knowledge will assist the trier of fact. However (absent creditable grounds supporting such a link), evidence that the moon was full on a certain night will not assist the trier of fact in determining whether an individual was unusually likely to have behaved irrationally on that night. Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 125 L.Ed.2d at 481-82 (citations omitted).

Among other things, Defendants cite the following testimony in support of their "no-fit" argument:

> Q. Now, tell us what opinions you have reached in this case.
>
> A. I believe more likely than not that Mr. Joiner's lung cancer was causally linked to cigarette smoking and PCB exposure. And by PCB exposure, I'm thinking also of PCBs and dioxins and dibenzofurans and related chemicals which frequently are found together in transformer fluids.

(Schecter Dep. at 61).

> Robert Joiner, by occupational history, was exposed at work, for a long period of time on a regular basis to PCBs and other transformer fluid contaminants

> routinely, after fires and high heat incidents, and when there was heating during the repair process. . . . Therefore, the initiating and promoting effects of the amounts of PCBs, dioxins and dibenzofurans was certainly enough to have contributed to his lung cancer, to the best of my medical and scientific opinion.

(Schecter Aff. ¶ 21.)

> Q. All right. If you would, Dr. Teitelbaum, would you simply tell us what opinions you have reached in this case? [18]
>
> A. Yes. I would say I have three opinions. [First, Joiner has lung cancer.]
>
> Secondly, it's clear that for a period of many years, Mr. Joiner worked as an industrial electrician and had exposure to various materials commonly used in the trade, including mineral oils contaminated with PCBs.
>
> And, three, that his lung cancer was caused by or contributer to in a significant degree by the materials with which he worked.
>
> . . . .
>
> Q. Have you been shown any documents that would reflect the presence of dibenzofurans, dibenzodioxins, or chlorinated benzene in any of the mineral oil on which Mr. Joiner worked on or around?
>
> A. I don't have any documents which would answer that question. There are, so far as I can tell, no quantitative analyses that have been supplied to me that answer how much and when.
>
> . . . .
>
> Q. Or if any; is that correct?
>
> A. I don't have any documents at all. I think that one simply has to look at the likely chemistry of the situation and what's known about PCBs man-

[18] Dr. Daniel Teitelbaum (M.D.) is one of Plaintiffs' experts.

ufactured in this period and assume that there was some furan present, that there may have been some dioxin present, depending on the particular fire and circumstance. There probably was some chlorinated benzene since that's almost always a contaminant.

(Teitelbaum Dep. at 28, 33-34).[19]

On the basis of an overwhelming body of scientific evidence which supports the position which I have taken, that cancer is a multi-factorial disease, I have outlined the elements of causation which are identifiable from Mr. Joiner's family, personal, medical and occupational history. I have specifically listed these factors in my deposition. I believe that his family history of cancer, his personal history of exposure to cigarette smoke and perhaps to silica, his medical history and his occupational history which included exposure to polychlorinated biphenyls, their contaminants, including polychlorinated [d]ibenzo-

[19] Dr. Teitelbaum's testimony is also unhelpful because of his assumptions regarding the rate at which Joiner was exposed to PCBs during his work:

Q Now, do you know how often, if at all, the mineral oil was contaminated with PCBs?

A No, I don't know that. As I said, I understand that there are documents, but I don't know from what era.

Q All right.

A I would say that from the era that we're talking about, virtually all of the mineral oil would have been contaminated within the ranges that we're talking about. I think it would be unusual for it not to be contaminated at that time.

Q All right. So for purposes of your rendering your opinion, are you assuming that virtually all the mineral oil was contaminated with PCBs?

A Yes.

Q Okay.

A With concentrations between 50 and a few thousand parts per million during this era of time.

(Teitelbaum Dep. at 45-46.) As noted earlier, about one in five of the City's transformers presented a PCB risk.

furans, mineral oil, mineral spirits and other material together were a sufficient and probable cause of Mr. Joiner's lung cancer. In my opinion, PCBs were a significant contributing cause to Mr. Joiner's lung cancer.

(Teitelbaum Aff., ¶ 12.)

The foregoing testimony makes it clear that Plaintiffs' experts assumed Joiner was exposed to furans and dioxins.[20] Moreover, this assumption is an integral part of the foundation for the experts' opinions that PCBs contributed to Joiner's lung cancer. However, as discussed above, Plaintiffs have failed to show a genuine dispute over whether furans and dioxins were in the PCBs to which Joiner was exposed. Thus, the testimony of Plaintiffs' experts manifestly does not fit the facts of this case, and is therefore inadmissible.[21]

[20] The court notes the following testimony by Dr. Schecter:

Q. What information do you have about the concentrations of PCBs, furans and dioxins in the mineral oil contained in the transformers that Robert Joiner worked around?

A. We have specific data back that came by fax yesterday, and I showed you my entire file, showing that there were PCBs in some of the mineral oil. And my general knowledge that dibenzofurans and dioxins are found in PCB-containing electrical transformer oils.

(Schecter Dep. at 84.)

[21] Dr. Robertson's testimony has no utility, for he failed to identify any specific chemicals as alleged promoters of Joiner's lung cancer:

I expect, based upon of course what further information comes to me, that is I qualify my expectation on that basis, that my —my expert opinion will be that this gentleman developed lung carcinoma at a very young age because the onset of that disease was promoted, supported, accelerated by his exposure to halogenated aromatic hydrocarbons.

(Robertson Dep. at 16.) Defendants assert that the term "halogenated aromatic hydrocarbons" describes a "broad category of chemicals." (Defendants' Brief at 15 n. 14.)

Assuming that Plaintiffs' experts had not made unfounded assumptions about furans and dioxins, Defendants still persuade the court that Plaintiffs' expert testimony would not be admissible. Defendants do this by attacking the conclusions that Plaintiffs' experts draw from the studies they cite.

Defendants initially argue that they are entitled to summary judgment because Doctors Robertson and Teitelbaum answered in the negative when asked if there was any credible evidence "as a scientific probability" that PCBs cause or promote small cell lung cancer in humans. (Robertson Dep. at 14; Teitelbaum Dep. at 110.) Stated another way, Defendants assert that they are entitled to summary judgment because there are no epidemiological studies which show that PCBs cause small cell lung cancer in humans. However,

> "a cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, such as use of tissue samples, standard tests, and patient examination, products liability law does not preclude recovery until a 'statistically significant' number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical."

Wells v. Ortho Pharmaceutical Corp., 788 F.2d 741, 745 (11th Cir.)(quoting *Ferebee v. Chevron Chem. Corp.*, 736 F.2d 1529, 1535 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984)), *cert. denied*, 479 U.S. 950 (1986). Thus, the absence of an epidemiological study in Plaintiffs' favor does not automatically foreclose their action.

Defendants attack the experts' reliance on animal studies with more success. Dr. Robertson testified regarding two studies of infant, suckling mice upon which Doctors Schecter and Teitelbaum relied. Defendants summarize Dr. Robertson's testimony as follows:

> Dr. Robertson admitted that his opinion that PCBs are "promoting agents" is based on only two studies in infant, suckling mice. (Robertson Depo., at 14-15.) . . . [A]s to those two studies, Dr. Robertson admitted that (1) the lung cancer promoted in the infant mice was not identified as small cell carcinoma (Robertson Depo., at 15), (2) he did not know whether the same effect had been produced in adult mice (Robertson Depo., at 23), (3) the tumors produced were dose-dependent, (Robertson Depo., at 26), and (4) after having administered a known initiating carcinogen, the mice were dosed with 100% PCBs by either injecting it directly into the peritoneum (the body cavity containing most vital organs) or directly into the stomach (Robertson Depo., at 27-28).[22]
>
> A review of the two studies themselves reveals that [the] infant mice developed alveolgenic adenomas, not small cell carcinomas. (Robertson Depo., Exhibits 2 & 3).[23]

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[22] Dr. Robertson testified that in one of the studies the mice were dosed with 500 milligrams of PCBs per kilogram, while in the other a range of doses (i.e., 50, 250, and 500 milligrams of PCBs per kilogram) was given. (Robertson Dep. at 26.)

[23] Defendants have not cited to the court evidence regarding the definition of "adenoma." The court judicially notices that it is "*a benign* tumor of a glandlike structure or of glandular origin." *Webster's Third New International Dictionary* 25 (Merriam-Webster 1986) (emphasis added). *See* footnote 7, *supra*. Despite the fact that an adenoma is a benign tumor, Dr. Robertson testified that the mice had developed a form of cancer:

> A I know of studies, and we have identified one of them, in which PCBs promote DMN-initiated carcinoma in the lung of mice.
>
> Q34 Is that article small cell carcinoma . . .?
>
> A It's not identified as such, that's correct.

(Robertson Dep. at 14-15.) Though copies of the mice studies were used as exhibits during Dr. Robertson's deposition, the ex-

(Defendants' Brief at 36.) Both Dr. Schecter and Dr. Teitelbaum relied on the mice studies in opining that PCBs promoted Joiner's lung cancer. (Schecter Dep. at 66-69; *see* Teitelbaum Dep. at 48, 78-81.)

Defendants assert that Plaintiffs' experts' reliance on the mice studies is unjustifiable because they "admittedly base their various opinions on the extrapolation of physical effects observed in laboratory test animals subjected to extremely high levels of PCBs." (Defendants' Brief at 35.) In support of this position, Defendants cite *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.1992), *cert. denied*, —— U.S. ——, 121 L.Ed. 2d 47 (1992), which contains the following passage:

> We do not mean to intimate that animal studies lack scientific merit or power when it comes to predicting outcomes in humans. Animal studies often comprise the backbone of evidence indicating biological hazards, and their legal value has been recognized by federal courts and agencies. . . .
>
> Here, the record's explanation of the animal studies is simply inadequate. Although the animal studies themselves may have been scientifically performed, the exact nature of these tests is explained only in general terms. The record fails to make clear why the varying doses of Bendectin or doxylamine succinate given to the rats, rabbits and *in vitro* animal cells would permit a jury to conclude that Bendectin more probably than not causes limb defects in children born to mothers who ingested the drug at prescribed doses during pregnancy. The analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects is too wide. Under such circumstances, a jury should not be asked to speculate on the issue of causation.

Id., 959 F.2d at 1360-61 (citations omitted).[24]

Defendants' argument persuades the court that Plaintiffs' experts' reliance on the mice studies is flawed for several reasons. First, there are only two studies. Second, the studies obviously used massive doses of PCBs. Finally, Dr. Teitelbaum implicitly admitted the preliminary nature of the mice studies' findings:

> Q Other than the studies by Lucy Anderson [i.e., the author of the mice studies], do you know of any other animal study where lung cancer was promoted in a species other than mice?
>
> A I don't think anybody's studied any other study. I think that now that the 1993 Anderson publication came out, I suspect you're going to see some more studies on that because now there seems to be a clean model that can be looked at.

(Teitelbaum Dep. at 87.) The court thus finds that Defendants have sufficiently called into question the validity of Plaintiffs' experts' reliance on the mice studies. Therefore, the burden shifts to Plaintiffs to demonstrate by a preponderance of proof that their experts' opinions are admissible.

Regarding the mice studies, Plaintiffs have chosen to proceed as if the only issue is whether animal studies can ever be a proper foundation for an expert's opinion. Plaintiffs assume Defendants' argument is that experts should never rely on animal studies as the basis for an expert

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hibits did not accompany the copy of the Robertson deposition that was filed with the court. Thus, the court is unable to review the studies themselves in order to clarify the confusion that exists over whether the mice in fact developed malignant tumors. However, in their brief Defendants repeatedly concede that a form of lung cancer occurred in the mice. The court thus proceeds from the standpoint that the mice did develop some type of lung cancer, but that the lung cancer was not of the small cell variety.

[24] *Turpin* predates *Daubert*. However, in *Daubert* the Supreme Court referred to *Turpin* with approval. *See Daubert*, 509 U.S. at ——-——, 113 S.Ct. at 2797-99, 125 L.Ed.2d at 484-85.

opinion. However, read as a whole, that is not Defendants' argument. (*See* Defendants' Brief at 32, 33 ["Valid scientific reasons exist for scientists to exercise extreme caution when interpreting animal studies"; "[t]his is not to say that animal studies have no legitimate role in scientific research, but it is certainly a limited one."].) Plaintiffs' argument addresses the question of reliance on animal studies in general, not the deficiencies that Defendants have highlighted in the experts' reliance on the animal studies at issue here. Plaintiffs' argument, being unresponsive to the issue at hand, does not persuade the court to change its finding that Plaintiffs' experts erred in relying on the mice studies to opine that PCBs caused Joiner's lung cancer "to a 'reasonable degree of medical certainty.' " *Wells*, 615 F.Supp. at 295.

Regarding epidemiological studies, Plaintiffs take issue with Defendants' claim that no such studies support Plaintiffs' position, for they assert that their experts "identify several epidemiological studies in support of their opinions." (Plaintiffs' Brief at 46 [footnote omitted].)[25]

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[25] Teitelbaum testified that he was aware of no studies which show that PCBs cause, contribute, or promote small cell lung cancer in humans. (Teitelbaum Dep. at 110-11.) Dr. Schecter confirmed that controlled studies which showed PCB to be a cancer promoter were done only on animals:

> Q. Again, your opinion that PCBs, dioxins and furans operate as promoters is based upon studies of laboratory animals only, is that true?
>
> A. The studies which tell us that PCBs, dioxins and dibenzofurans are promoters of cancer were developed through laboratory animals and we have belief that they are relevant to humans. We test them on animals. We beleive that's relevant to humans.
>
> Q. Your opinion about PCBs, dioxins and furans being promoters is based upon studies of animals?
>
> A. Yes. And my reason for believing this is relevant to human studies is because all government agencies concerned with health believe that this is the case and that we can usually predetect, because humans also are in the animal kingdom. Humans cells are nuclei, cytoplasm, mitocho[n]dria, endoplasmic reticulum and respond in similar fashion.

(Schecter Dep. at 68-69.)

[26] One such quote is that "[s]tudies of the metabolic fate [sic; rate?] of these substances sustain the *plausibility* of a carcinogenic action" (emphasis added). The mere plausibility of carcinogenic action does not establish causation. *See Turpin*, 959 F.2d at 1360 ("[The plaintiffs' experts] testify that the animal studies show that Bendectin is 'capable of causing,' 'could cause' or its effects are 'consistent with causing' birth defects, not that it probably causes birth defects in general or that it did in this case. In short, they testify to a possibility rather than a probability.").

[27] With one exception, neither party has provided the court with a copy of the studies cited in the briefs. (The one exception is Plaintiffs' provision of the Zack & Musch study discussed below.) Thus, the court for the most part has had to rely on the excerpts from the studies that the parties have provided in their briefs.

Plaintiffs assert that the studies their experts cite "demonstrate a positive correlation between exposure to PCB and lung cancer." (Plaintiffs' Brief at 11.) However, in every case Defendants show that the studies are either equivocal or not helpful to Plaintiffs.

Plaintiffs offer selected quotes from Bertazzi, et al., *Cancer Mortality of Capacitor Manufacturing Workers*, 11 Am.J.Indus.Med. 165 (1987), in support of their position. (*See* Plaintiffs' Brief at 11.)[26] Defendants note, however, that the Bertazzi study contains the following conclusion:

> There were apparently no grounds for associating lung cancer deaths (although increased above expectations) and exposure in the plant. The numbers were small, the value of the risk estimate was not statistically significant, and such risk had never been suggested before.

(Defendants' Reply at 7 [quoting Bertazzi, *supra*, at 172].)[27]

Plaintiffs offer selected quotes from Judith A. Zack & David C. Musch, *Mortality of PCB Workers at the Mon-*

santo Plant in Sauget, Illinois (1979), an unpublished study that Monsanto funded. (Plaintiffs' Brief at 12-13.) Defendants note that in a later version of the study (which they assert was prepared with a view toward publication) the study's authors specifically stated that "[w]hile many of the cancer-specific SMRs exceed 100, none are statistically significant." (Defendants Reply, Ex. C at 7.)[28] At least with regard to lung cancer, the original study that Plaintiffs cite essentially contains the same statement, albeit in a longer fashion:

> For all males, there were 30 deaths observed and 22.88 expected (Table 4). . . . The SMR for lung cancer was high at 278. The only statistically significant difference seen in this table is seen for diseases of the circulatory system, exclusive of arteriosclerotic disease. Nine deaths were observed with 3.98 expected, yielding a SMR of 226. Table 5 shows the overall SMR remains high for white males at 133. . . . There were 3 deaths observed from lung cancer with 0.94 expected, yielding a SMR of 319. For the category of circulatory disease, exclusive of arteriosclerotic disease, the SMR was 526 with 7 observed and 1.83 expected deaths. This difference was the only one of statistical significance in this table.

Plaintiffs assert that "[a]nother study of interest is a study of PCB exposed workers in a Norwegian cable manufacturing company. A statistically significant excess of deaths from lung cancer was observed. Ten deaths from lung cancer were observed when only 3.9 were expected." (Plaintiffs' Brief at 13.) Defendants note that the study "never mentions PCBs and does not involve 'PCB-exposed workers.' It reports a statistically significant excess of cases of lung cancer in a small cohort of

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[28] "Ratios of observed to expected number of deaths [are] expressed as standardized mortality ratios (SMRs)." (Defendants' Reply, Ex. C at 6.)

cable workers exposed to mineral oil, whose exposure was also confounded by exposure to asbestos and cigarette smoke." (Defendants' Reply at 8.) The study concluded as follows:

> The present study has shown a statistically significant excess of cases of lung cancer in a small cohort of oil exposed cable workers. This result cannot be accounted for by excess smoking alone and exposure to non-severely refined, low viscosity, and high viscosity oils must be considered as an important causative factor. For reasons discussed above the results presented here are not necessarily relevant to all other types of mineral oils. Further follow up of this population and studies of other groups with well defined exposure to oils are needed before any firm conclusions may be drawn regarding the carcinogenicity of mineral oil products to the human lung.

(Defendants' Reply at 8 n. 8 [quoting Ronneberg, et al., *Mortality and Incidence of Cancer Among Oil Exposed Workers in a Norwegian Cable Manufacturing Company Part 2 Mortality and Cancer Incidence in 1953-84*, 45 British J. Indus. Med. 595, 601 (1988)].)

The last study Plaintiffs cite is Ikeda, et al., *A Cohort Study on Mortality of Yusho Patients—A Preliminary Report*, 78 Fukuoko Acta Med. 297 (1987), which Plaintiffs assert was summarized in a publication entitled *World Health Organization's International Programme on Chemical Safety, Polychlorinated Biphenyls and Terphenyls* 449 (2d Ed.1993). The "Yusho" incident involved Japanese people who were accidentally exposed to toxic substances. The report states that " '[a] statistically significant excess mortality was seen for malignant neoplasms, cancer of the liver and cancer of the lung, trachea, and bronchi in males.' " (Plaintiffs' Brief at 13.)

Defendants respond to this study as follows:

> The [Ikeda] report was published in English by Kuratsune, et al., "Analysis of Deaths Seen Among Pa-

tients With Yusho—A Preliminary Report," *Chemosphere*, Vol. 16, Nos. 8/9, pp. 2085-2088 (1987). As indicated by the title, it is a "preliminary report" of an "analysis of deaths," *not* an epidemiological study. No regression analysis was done and the authors did not control for cigarette smoking, asbestos exposure, or other causes of cancer. Most significant, however, is the fact that, although the deaths were observed in Yusho patients, the authors *did not examine if the observed excess risks might be related to the intake of toxic rice oil.* Kuratsune, p. 2087.

(Defendants' Brief at 10 [emphasis in original].) Dr. Schecter's testimony reveals why the omission regarding toxic rice oil is so significant:

> A. . . . We have a voluminous data on human response in Yusho and Yuchem to humans exposed to PCBs, dibenzofurans and dioxins.
>
> Q. Now, in those two incidents, the Yusho and Yuchem, in both of those [incidents], what was the concentration of PCBs, was it a 65 percent concentration, was it 650 parts per million Aroclor or some equivalent?
>
> A. I don't remember what it was. *It was PCB and dibenzofuran and dioxin contamination of rice oil which was used to cook food.* I don't think anyone can be certain of what the intake was.

(Schecter Dep. at 91 [emphasis added].) Finally, Dr. Teitelbaum did not find much significance in the Yusho report:

> Q. . . . . What, if any, epidemiological studies have you reviewed in reaching your opinion?
>
> A. . . . .
>
> . . . You've got Kuratsune's studies from Japan. You've got a few cases of lung cancer there. They're not very convincing, as the Japanese lifestyle is different. There's—it's, again, suggestive but not convincing.

(Teitelbaum Dep. at 89-90.) The limitations in the Yusho study (e.g., failure to investigate exposure to other potential carcinogens), the fact that the persons studied were exposed to furans and dioxins, and the fact that one of Plaintiffs' own experts has a low opinion regarding the relevance of the Yusho study together combine to convince the court that the study has no utility for Plaintiffs' purposes.

In *Daubert*, the Supreme Court noted that under Rule 702 "[t]he subject of an expert's testimony must be 'scientific . . . knowledge.' The adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation." *Id.*, 125 L.Ed.2d at 480-81 (ellipsis in original) (footnote omitted). The court need not address whether the studies that Plaintiffs' experts rely upon were conducted in a scientific manner, for the studies simply do not support the experts' position that PCBs *more probably than not* promoted Joiner's lung cancer. That is, the court is not persuaded by a preponderance of proof that the studies support the "knowledge" the experts purport to have, i.e., that PCBs, "to a 'reasonable degree of medical certainty,' " *Wells*, 615 F.Supp. at 295, promote small cell lung cancer in humans). *See Turpin*, 959 F.2d at 1360 ("The analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects is too wide."); *cf. Wells*, 788 F.2d at 745 ("[T]he basic methodology employed to reach . . . a conclusion [must be] sound."). The court is persuaded that the opinions of Plaintiffs' experts do not rise above "subjective belief or unsupported speculation." [29]

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[29] Summary judgment for Defendants would be in order even if the testimony of Plaintiffs' experts were admissible, for the court believes that no reasonable juror could find that PCBs caused Joiner's lung cancer given the flawed nature of Plaintiffs' experts opinions. *Cf. Elkins v. Richardson-Merrell, Inc.*, 8 F.3d 1068, 1071 (6th Cir.1993) ("We construe *Turpin* to treat the plaintiff's ex-

Plaintiffs' experts opinions that PCBs promoted Joiner's lung cancer are inextricably bound up with their unfounded assumption that Joiner was exposed to furans and dioxins. Moreover, the court finds that Plaintiffs have failed to show by a preponderance of proof that their experts' opinions regarding the PCB/lung cancer link are admissible under the standards set out in Rule 702 and explicated in *Daubert*. Therefore, Defendants are entitled to summary judgment on all of Plaintiffs' claims.

CONCLUSION

Accordingly, Defendants' joint motion for summary judgment [#46-1] is GRANTED. Defendants' request for oral argument on their motion for summary judgment [#47-1] and Plaintiffs' request for oral argument on Defendants' motion for summary judgment [#55-1] are DENIED. GE's motion requesting supplemental brief [#67-1] is DENIED. The Clerk is DIRECTED to enter judgment in Defendants' favor on all of Plaintiffs' claims.

SO ORDERED, this 16 day of September, 1994.

/s/ Orinda D. Evans
ORINDA D. EVANS
UNITED STATES DISTRICT JUDGE

ENTERED ON DOCKET
SEP. 20 1994
BY L.D.T. CLERK
DEPUTY CLERK

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pert opinion indicating a basis of support for the plaintiff's theories in animal studies to be admissible but 'simply inadequate . . . [to] permit a jury to conclude that Bendectin more probably than not causes limb defects.' *Id.* at 1360.") (ellipsis and brackets in original).

APPENDIX D

[Filed Sept. 20, 1994]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Civil Action No. 1:92-cv-2137-ODE

ROBERT K. JOINER, KAREN P. JOINER
Plaintiffs,

vs.

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORP.,
MONSANTO COMPANY
Defendants.

JUDGMENT

This action having come before the court, Orinda D. Evans, United States District Judge, for consideration of the action, and the court having decided same, it is

Ordered and Adjudged that the plaintiffs, Robert K. and Karen P. Joiner, take nothing, that the action be dismissed, and that the defendant, General Electric Company, Westinghouse Electric Corporation, Monsanto Company, recover from the plaintiffs the costs of this action.

Dated at Atlanta, Georgia, this 16th day of September, 1994.

LUTHER D. THOMAS
Clerk

By: /s/ Diane Taylor
DIANE TAYLOR
Deputy Clerk

APPENDIX E

Federal Fules of Evidence

Rule 104

Preliminary Questions

(a) Questions of Admissibility Generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

(b) Relevancy conditioned on fact. When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

(c) Hearing of jury. Hearings on the admissibility of confessions shall in all cases be conducted out of the hearing of the jury. Hearings on other preliminary matters shall be so conducted when the interests of justice require, or when an accused is a witness and so requests.

(d) Testimony by accused. The accused does not, by testifying upon a preliminary matter, becomes subject to cross-examination as to other issues in the case.

(e) Weight and credibility. This rule does not limit the right of a party to introduce before the jury evidence relevant to weight or credibility.

* * * *

Rule 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an

expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

* * * *

Rule 706

Court Appointed Experts

(a) Appointment. The court may on its own motion or on the motion of any party enter an order to show cause why expert witnesses should not be appointed, and may request the parties to submit nominations. The court may appoint any expert witnesses agreed upon by the parties, and may appoint expert witnesses of its own selection. An expert witness shall not be appointed by the court unless the witness consents to act. A witness so appointed shall be informed of the witness' duties by the court in writing, a copy of which shall be filed with the clerk, or at a conference in which the parties shall have opportunity to participate. A witness so appointed shall advise the parties of the witness' findings, if any; the witness' deposition may be taken by any party; and the witness may be called to testify by the court or any party. The witness shall be subject to cross-examination by each party, including a party calling the witness.

(b) Compensation. Expert witnesses so appointed are entitled to reasonable compensation in whatever sum the court may allow. The compensation thus fixed is payable from funds which may be provided by law in criminal cases and civil actions and proceedings involving just compensation under the fifth amendment. In other civil actions and proceedings the compensation shall be paid by the parties in such proportion and at such time as the court directs, and thereafter charged in like manner as other costs.

(c) Disclosure of appointment. In the exercise of its discretion, the court may authorize disclosure to the jury of the fact that the court appointed the expert witness.

(d) Parties' experts of own selection. Nothing in this rule limits the parties in calling expert witnesses of their own selection.

(3)

Supreme Court, U.S.
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No. 96-188

IN THE

Supreme Court of the United States

October Term, 1996

GENERAL ELECTRIC COMPANY, WESTINGHOUSE ELECTRIC CORPORATION, AND MONSANTO COMPANY,
Petitioners,

v.

ROBERT K. JOINER AND KAREN P. JOINER,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the judgment of the court below was based simply on its holding, reached under *de novo* review, that the district court had applied an erroneous construction of Fed. R. Evid. 702 in rendering its admissibility ruling.

2. Whether, if the abuse-of-discretion review standard is somehow relevant to the judgment below, this Court should grant review in order to ensure that in applying well-accepted standards for abuse-of-discretion review of district court evidentiary findings, precisely the same terminology will be used in every circuit.

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BRIEF FOR RESPONDENTS IN OPPOSITION

The petition in this case rests entirely on two sentences in the decision below that address the abuse-of-discretion standard for contested district court findings of fact. App. 4a. "This Court, however, reviews judgments, not statements in opinions," and for that reason this Court has a "duty to look beyond the broad sweep of the language and determine for [itself] precisely the ground on which the judgment rests." *Black v. Cutter Laboratories*, 351 U.S. 292, 297-98 (1956) (citations omitted). The two sentences seized on by petitioners have, in fact, nothing to do with this case, which was argued and won below on the ground that the district court had committed legal error, reviewable *de novo*, in its construction of Fed. R. Evid. 702.

Even if these two sentences were somehow relevant to the judgment below, there is nothing to petitioners' claim that an important circuit conflict exists over the standard of review for trial court decisions excluding expert testimony. "'[A]buse of discretion' . . . is 'a verbal coat of . . . many colors.'" Hon. Henry J. Friendly, *Indiscretion About Discretion*, 31 Emory L.J. 747, 763 (1982) (quoting *United States v. L.A. Tucker Truck Lines*, 344 U.S. 33, 39 (1952) (Frankfurter, J., dissenting)). All circuits use an abuse-of-discretion standard in reviewing trial court factfinding concerning the admissibility of expert testimony, although slight differences in the terminology used to describe the standard do exist. There is no need for review in this area unless and until a case emerges where it appears that the result would be different if a holding in another circuit were applied. This is not such a case.

STATEMENT OF THE CASE

1. Introduction. This diversity action, arising under Georgia tort law, was instituted by respondent Robert K. Joiner and his wife, respondent Karen P. Joiner (for simplicity, "Joiner"). Beginning in 1973, Joiner worked for the City of Thomasville, Georgia, as an electrician responsible for maintaining and repairing electrical transformers and voltage regulators. App. 2a. For over a decade, in the course of his employment Joiner came into frequent contact with dielectric fluid distributed by petitioners General Electric Company and Westinghouse Electric Corporation.

He frequently breathed it in close quarters and often absorbed it through his skin. App. 2a-3a. It is undisputed that as a result of his workplace exposure to dielectric fluid, Joiner was exposed to polychlorinated biphenyls ("PCBs"), a chemical produced by petitioner Monsanto Company. App. 2a, 35a-37a. The parties disagree on the effects of that exposure. In addition to alleging that the exposure to PCBs itself was a battery under Georgia law, Joiner alleges that the exposure contributed to his development of lung cancer at the unusually early age of 37 and seeks recovery under strict liability, negligence, fraud, and punitive damages theories for petitioners' role in contributing to his injury. App. 39a-40a.

Petitioners denied that exposure to their products injured Joiner in any way. After full discovery on causation issues, during which both sides deposed each other's experts, petitioners filed a motion for summary judgment arguing that Joiner could not prove that their products contributed to his development of lung cancer at an abnormally early age. The motion relied solely on the discovery materials developed at that point in the case; petitioners did not submit with their motion any new expert testimony (by way of affidavit, for example) attacking the testimony of Joiner's experts. Nonetheless, with his summary judgment opposition, Joiner included affidavits from two concededly qualified experts laying out the basis of his claim that petitioners had contributed to the development of his lung cancer. Petitioners made no attempt to impeach the validity of these affidavits with affidavits from their experts. Nor did petitioners move to strike the affidavits, or to exclude the underlying testimony through a motion *in limine*.

2. District Court Holding. Both sides requested oral argument on the issues raised in their papers. The district court did not grant these requests. Nor did it hold an evidentiary hearing to evaluate the live testimony of Joiner's experts regarding their proposed testimony. Instead, the district court granted summary judgment in full and dismissed Joiner's complaint. The district court's grant of summary judgment rested on two separate grounds, one under Fed. R. Civ. P. 56 on the sufficiency of Joiner's evidence, and another under Fed. R. Evid. 702 on the admissibility of his experts' testimony.

On the first ground, the district court held under Rule 56(c) that petitioners had "made a satisfactory showing that there is insufficient evidence to establish that Joiner was exposed to furans or dioxins" (toxic chemicals often present with PCBs). App. 46a. Reviewing the record, the district court then held under Rule 56(e) that Joiner's evidence was "insufficient to allow a jury to determine that Joiner was exposed to furans," App. 49a, and was also insufficient to establish that "Joiner was exposed to dioxins." App. 51a. The district court then used this holding to rule all of Joiner's expert testimony inadmissible, on the premise that the testimony was "inextricably bound up with the experts' assumption that Joiner was exposed to furans and dioxins." App. 53a; *see also* App. 57a (stating that "Plaintiffs' experts assumed Joiner was exposed to furans and dioxins. . . . [A]s discussed above, Plaintiffs have failed to show a genuine dispute over whether furans and dioxins were in the PCBs to which Joiner was exposed.").

As a second ground for summary judgment, the district court ruled all of Joiner's expert testimony inadmissible under Rule 702, focusing explicitly on "the conclusions that Plaintiffs' experts draw from the studies they cite." App. 58a. The district court explained that it was "not persuaded" that these conclusions were anything more than subjective speculation. App. 67a. The district court focused in particular on whether, in its view, some of the specific studies cited by Joiner's experts supported the specific conclusions that they had reached. *See, e.g.*, App. 62a ("Plaintiffs' experts erred in relying on the mice studies to opine that PCBs caused Joiner's lung cancer"); App. 63a (opining that other "studies are either equivocal or not helpful to Plaintiffs"); App. 63a-64a (complaining that only "selected quotes" were used from one study).

3. The Court of Appeals' Decision. On appeal, Joiner did not attack any exercise of the district court's discretion, and discussed none of the district court's criticisms of the specific scientific data involved in this case. Rather, he argued for *de novo* review of both grounds for summary judgment. The court of appeals agreed, conducted *de novo* review, accepted Joiner's legal arguments, and reversed the district court's grant of summary judgment.

On the first ground for summary judgment involving Rule 56, Joiner argued that the district court "erred as a matter of law in ruling the testimony of Joiner's experts inadmissible on the ground that the experts' opinions 'do not fit the facts in this case because the opinions are inextricably bound up with the experts' assumption that Joiner was exposed to furans and dioxins.'" Brief of Plaintiffs-Appellants, filed Jan. 29, 1995 ("Joiner Br."), at 22 (quoting App. 53a). Joiner argued that "[t]he district court cited no evidence in support of its assertion" that this assumption was integral, and that "[n]owhere in their depositions or affidavits did Joiner's experts indicate that their opinions hinged on exposure to furans or dioxin, and that their conclusions would change if nonexposure were proved." *Id.* at 23. On *de novo* review, the Eleventh Circuit agreed and reversed on this ground, noting that each expert had testified that PCBs alone cause cancer, so that it was "immaterial whether there were furans and dioxin in the fluid." App. 14a. In any event, the court held, "a genuine dispute . . . exists over whether furans and dioxins could have been present in the dielectric fluid," App. 14a-15a, reviewing the record evidence on this point *de novo* as it was required to do under Rule 56. *See* App. 15a-16a.

On the second ground for summary judgment involving Rule 702, Joiner's argument was similarly straightforward. After noting that "errors in the construction and application of the Federal Rules of Evidence are reviewed *de novo*," Joiner Br. at 4 (citing *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 (1988)), Joiner argued that "[t]he district court's entire analysis of Joiner's expert testimony, *see* Opinion at 21-39 [App. 51a-68a], is based on a misunderstanding of Fed. R. Evid. 702." Joiner Br. at 11. Relying on this Court's statement that the "focus" of analysis under Rule 702, "of course, must be solely on principles and methodology, not on the conclusions that they generate," *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2797 (1993), Joiner argued that by "bas[ing] its inadmissibility ruling on an examination of the experts' particular conclusions," and crediting petitioners' attacks on those conclusions, "the district court's whole analytical framework" was "erroneous as a matter of law." Joiner Br. at 14-16.

The Eleventh Circuit agreed and reversed on this ground also. Summarizing *Daubert*'s construction of Rule 702, the court of appeals emphasized that the only issue under Rule 702 is whether an expert's methodology is scientifically valid. Thus, trial judges must "be careful not to cross the line between deciding whether the expert's testimony is based on 'scientifically valid principles' and deciding upon the correctness of the expert's conclusions." App. 6a (quoting *Daubert*, 113 S. Ct. at 2796). A district court, it held, "is not to weigh or choose between conflicting scientific opinions, or to analyze and study the science in question in order to reach its own scientific conclusions from the material in the field." App. 7a; *see also* App. 11a ("the district court's focus is a narrow one and does not encompass deciding which expert's conclusions are better reasoned or more appealing. Nor should the court make independent scientific judgments on the basis of individual studies.").

After setting out this description of the content of the Rule 702 standard, the court of appeals then held that the district court had committed legal error in failing to apply the standard. It noted that the district court had addressed only half the studies analyzed by Joiner's experts and, relying only on brief and highly critical summaries, had "then accepted defendants' criticisms of the conclusions reached in those studies." App. 13a & n.9 (citing App. 67a). This approach, the court pointed out, was wrong as a matter of law: "As *Daubert* makes clear, the district court may not decide whether an expert's opinions are correct, but merely whether the bases supporting the conclusions are reliable." App. 13a (citation omitted). After reviewing the uncontradicted evidence on the validity of the methodology employed by Joiner's experts, *see* App. 8a-11, and specifically noting that "defendants do not challenge" the fact that the experts' methodology has been generally accepted as valid for centuries, App. 10a-11a, the Eleventh Circuit reversed. It held that the district court had erred as a matter of law under Rule 702 in "exclud[ing] the testimony because it drew different conclusions from the research than did each of the experts"; instead, the district court was obligated to allow "the jury to decide the correctness of competing expert opinions." App. 13a.

REASONS FOR DENYING THE PETITION

The petition should be denied for two independent reasons.

I. THE QUESTION IS NOT PROPERLY PRESENTED BECAUSE THE JUDGMENT BELOW IS BASED ON THE HOLDING, UNDER *DE NOVO* REVIEW, THAT THE DISTRICT COURT APPLIED AN ERRONEOUS CONSTRUCTION OF FED. R. EVID. 702

Certiorari is unwarranted here, first and foremost, because the question raised in the petition, concerning the nature of the standard of review for contested district court factfinding under Rule 702, has nothing to do this case.

The petition rests entirely on two sentences in the court of appeals' decision in which the court set out the abuse-of-discretion standard for review of contested findings of fact. *See* App. 4a. However, petitioners ignore that immediately following these two sentences the court stated that "[t]o the extent that the district court's ruling turns on an interpretation of a Federal Rule of Evidence, our review is plenary." App. 5a. As already explained, this is the only standard of review that turned out to be relevant to the Eleventh Circuit's decision reversing the grant of summary judgment: Joiner's sole Rule 702 argument was that the district court had erred as a matter of law by focusing not on his experts' methodology but, quite explicitly, on their particular conclusions, and the court ruled for Joiner on this basis. See pp. 3-5, *supra*.

Because this Court "reviews judgments, not statements in opinions," *Black v. Cutter Laboratories*, *supra*, 351 U.S. at 297, the fact that the Eleventh Circuit mentioned the abuse-of-discretion review standard for district court factfinding as part of a routine section of its opinion (the kind of general summary that is contained in countless appellate opinions) does not open the way for review. Nowhere do petitioners demonstrate that the abuse-of-discretion review standard had anything to do with the court of appeals' *judgment*. Indeed, petitioners concede that the key holding was "that 'we find that the district court improperly assessed the admissibility of the proffered scientific expert testimony.'" Pet. at 4 (quoting App. 2a) — in other words, that the

district court simply used the wrong approach in assessing the testimony under Rule 702. See pp. 4-5, *supra*. Petitioners' complaint that the court of appeals mentioned "materials not cited by any party in the District Court," Pet. at 4 (citing App. 16a), hardly demonstrates that it was conducting abuse-of-discretion review under Rule 702. Rather, this part of the court of appeals' opinion was merely conducting *de novo* review of whether a genuine issue existed on exposure to furans and dioxin. See p. 4, *supra*.

Nor are petitioners correct that the judges on the panel "disagreed as to the proper standard and nature of appellate review of district court rulings under *Daubert*." Pet. at 3. To the contrary, the concurrence actually reinforced the fact that the judgment below rested on *de novo* review of the district court's error of law in the overly broad scope of its analysis under Rule 702. It emphasized: "The *sufficiency* of the evidence and the *weight* of the evidence . . . are beyond the scope of the *Daubert* analysis. Whether the conclusions advanced from the stated premises in fact follow and the persuasiveness of these conclusions in the ultimate resolution of competing opinions, are questions appropriately left to the finder of fact." App. 16a-17a.

The dissent further confirmed that the judgment below rested on *de novo* review of the legal standard applied by the district court. The dissent simply disagreed with the majority's construction of Rule 702 and argued that the district court's construction was correct. *See* App. 21a ("the majority errs by first applying the reliability prong of *Daubert* to the experts' opinions as a whole, and then applying the relevancy prong."); App. 30a ("I caution against using the majority's approach that applies each *Daubert* prong to the testimony at a whole. I would approve the trial court's step-by-step approach"). This analysis of the proper construction Rule 702 has nothing to do with the standard of review for contested factual findings.

Of course, the dissent did address the standard-of-review topic, but only as an aside, to offer "a more precise explanation of the standard of review," App. 18a, by providing "clear guidance" with "terminology that is firmly established in the jurisprudence of this and other circuits." App. 19a. *See* App. 19a-21a & n.1. Moreover,

far from disagreeing with the majority's boilerplate statement on the standard of review, the dissent endorsed that analysis (albeit with minor suggestions for appropriate terminology). The dissent noted that whether the district court "properly applied Rule 702. . . is a question of law," App. 19a (the standard relevant to the judgment below). It is also quite plain from the dissent that the abuse-of-discretion analysis for district court factfinding where evidence has been excluded, described by the majority in dicta, is *not* a new and separate review standard; rather, it is simply a minor aspect of the traditional abuse-of-discretion review standard. *See* App. 18a ("In applying a 'particularly stringent' review, we do not change the threshold of review, but conduct a searching review of the record (i.e., take a 'hard look') while maintaining the proper standard of review.") (quoting App. 4a) (citations omitted).

II. IN ANY EVENT, THE QUESTION IS NOT WORTHY OF REVIEW BECAUSE THE CIRCUITS ARE IN BROAD AGREEMENT ON THE SUBSTANTIVE CONTENT OF EVIDENTIARY ABUSE-OF-DISCRETION REVIEW

As Judge Smith's dissent itself makes obvious enough, there is widespread agreement among the circuits over the appropriate standard of review in cases involving expert testimony, and nothing contained in the majority decision is out of step with settled law. Thus, even if the two sentences seized on by petitioners were somehow relevant to the judgment below — despite Joiner's reliance in his Rule 702 argument on the *de novo* review standard and the Eleventh Circuit's acceptance of Joiner's Rule 702 argument — there would still be no reason to grant review. The petition addresses only minor differences in use of terminology that are of no substantive importance, as a brief review of the caselaw reveals.

Notably absent from petitioners' review of how the circuits are supposedly "completely split" over whether to use a "manifestly erroneous" review standard or an "abuse of discretion" review standard, *see* Pet. at 6-11, is any discussion of federal appellate cases addressing whether there is any practical difference between the two standards. In fact, several circuits, in decisions studiously

ignored by petitioners, have addressed exactly this point. In *United States v. Rahm*, 993 F.2d 1405 (9th Cir. 1993), for example, the Ninth Circuit explained:

> We have sometimes described our standard of review in the area of expert testimony as "abuse of discretion" and sometimes as "manifest error." On occasion, we have used both characterizations.
>
> * * *
>
> We note that general adoption of the "abuse of discretion" characterization would bring this area into line with the rest of our law of evidence. . . . The "manifest error" characterization apparently emanates from a Supreme Court decision preceding the judiciary's efforts to settle on a limited number of review characterizations. *See Salem v. United States Lines Co.*, 370 U.S. 31, 35 (1962). There appears to be no practical difference between the two verbal formulae, so their vestigial co-existence serves no obvious purpose. Accordingly, it would be sensible to settle upon a uniform practice of characterizing our standard of review as "abuse of discretion" and abiding by it in all future cases . . . although for purposes of this opinion, it makes no difference which of the two terms — "abuse of discretion" or "manifest error" — we use.

Id. at 1409-10 (citations omitted). Likewise, in *Phillips Oil Co. v. OKC Corp.*, 812 F.2d 265, 280 & n.32 (5th Cir.), *cert. denied*, 484 U.S. 851 (1987), the Fifth Circuit noted that some of its cases had used the "manifestly erroneous" language for review of Rule 702 factfinding and some had used "abuse of discretion" language, but that "[w]e construe these various statements of the standard of review to be harmonious." *See also United States v. Boney*, 977 F.2d 624, 628 n.2 (D.C. Cir. 1992) (the two standards amount to "the same test").

Indeed, as the following survey of representative cases shows, all circuits, including the supposedly "extreme" Third and Eleventh Circuits, Pet. at 6 (whose doctrine petitioners typecast on the basis of only two decisions), apply the same standard when reviewing a district court's decision on the admission of expert testimony, using

the descriptions "abuse of discretion" and "manifestly erroneous" interchangeably — indeed, often together.

First Circuit — *United States v. Cartagena-Carrasquillo*, 70 F.3d 706, 710, 712 (1st Cir. 1995) (noting that decision to exclude expert testimony is "entitled to great deference," and holding that "[t]here was no abuse of discretion in excluding the testimony"); *United States v. Sepulveda*, 15 F.3d 1161, 1183 (1st Cir. 1993) ("a trial judge's rulings in this sphere should be upheld 'unless manifestly erroneous'") (quoting *Salem v. United States Lines Co.*, 370 U.S. 31, 35 (1962), *cert. denied*, 114 S. Ct. 2714 (1994)).

Second Circuit — *In re Air Disaster at Lockerbie Scotland on December 21, 1988*, 37 F.3d 804, 824 (2d Cir. 1994) ("trial court did not abuse its discretion in excluding the testimony of defense experts"), *cert. denied*, 115 S. Ct. 934 (1995); *United States v. Onumonu*, 967 F.2d 782, 786 (2d Cir. 1992) ("a district court's decision to exclude expert testimony is to be reviewed under the abuse-of- discretion standard. Therefore, we may reverse . . . if we conclude that the trial court's decision is 'manifestly erroneous'") (quotes and citations omitted).

Third Circuit — *Government of Virgin Islands v. Sanes*, 57 F.3d 338, 341 (3d Cir. 1995) ("district court did not abuse its discretion in excluding" expert testimony); *Marco v. Accent Publishing Co., Inc.*, 969 F.2d 1547, 1552-53 (3d Cir. 1992) ("trial court has broad discretion over whether to admit or exclude expert testimony"); *United States v. Agnes*, 753 F.2d 299, 303 (3d Cir. 1985) ("district court has broad discretion to exclude expert testimony," and its decisions "will be sustained unless they are manifestly erroneous").

Fourth Circuit — *United States v. Powers*, 59 F.3d 1460, 1471 (4th Cir. 1995) ("We review the district court's refusal to admit scientific evidence for abuse of discretion"); *United States v. Grandison*, 780 F.2d 425, 433 (4th Cir. 1985) ("exclusion of expert evidence . . . is to be sustained unless manifestly erroneous") (quoting *Salem*).

Fifth Circuit — *Eiland v. Westinghouse Elec. Corp.*, 58 F.3d 176, 180 (5th Cir. 1995) ("exclusion of expert testimony is a matter left to the discretion of the trial court, and that decision will not be disturbed on appeal unless it is manifestly erroneous"); *Rosado v. Deters*, 5 F.3d 119, 124 (5th Cir. 1993) (stating that district court's ruling "must be sustained unless manifestly erroneous," and then "find[ing] no abuse of discretion" in refusal to admit expert testimony).

Sixth Circuit — *American & Foreign Ins. Co. v. General Elec. Co.*, 45 F.3d 135, 137 (6th Cir. 1995) (trial court "has broad discretion in the matter of the admission or exclusion of expert evidence, and [its] action is to be sustained unless manifestly erroneous") (quoting *Salem*); *Mayhew v. Bell S.S. Co.*, 917 F.2d 961, 962 (6th Cir. 1990) ("we will sustain the [district court's] action unless it is manifestly erroneous. Thus, we review for an abuse of discretion") (citation omitted).

Seventh Circuit — *Deimer v. Cincinnati Sub-Zero Products, Inc.*, 58 F.3d 341, 344 (7th Cir. 1995) (stating that district court's decision "is to be sustained on appeal unless manifestly erroneous," then holding that "we certainly cannot say that the district court abused its discretion" in excluding expert testimony) (quotation and citation omitted); *Mercado v. Ahmed*, 974 F.2d 863, 871 (7th Cir. 1992) ("we review a district court's decision to exclude expert testimony under an abuse of discretion standard" and "the trial court's determination will be affirmed unless it is 'manifestly erroneous'") (quotations omitted).

Eighth Circuit — *United States v. Van Dyke*, 14 F.3d 415, 422 (8th Cir. 1994) (district court's "decision to exclude expert testimony is accorded broad discretion, and will be upheld unless it is manifestly erroneous"); *United States v. Cantrell*, 999 F.2d 1290, 1292 (8th Cir. 1993) ("A district court has broad discretion to admit or exclude expert testimony, and we will sustain that decision unless it was 'manifestly erroneous'") (quoting *Salem*), *cert. denied*, 114 S. Ct. 885 (1994).

Ninth Circuit — *United States v. Quintero*, 21 F.3d 885, 893 (9th Cir. 1994) ("We review the district court's decision to exclude expert testimony only for manifest error or abuse of discretion"; "there is 'no practical difference' between the two standards") (quoting *Rahm*, *supra*, 993 F.2d at 1410).

Tenth Circuit — *Getter v. Wal-Mart Stores, Inc.*, 66 F.3d 1119, 1124 (10th Cir. 1995), *cert. denied*, 116 S. Ct. 1017 (1996) (affirming ruling excluding expert testimony that "was neither manifestly erroneous nor an abuse of discretion"); *Werth v. Makita Elec. Works, Ltd.*, 950 F.2d 643, 647 (10th Cir. 1991) (trial court's ruling "will not be overturned unless it is manifestly erroneous or an abuse of discretion").

Eleventh Circuit — *Hibiscus Assoc. v. Bd. of Trustees*, 50 F.3d 909, 917 (11th Cir. 1995) (trial court has "broad discretion to exclude expert testimony, and his action will be upheld unless it is manifestly erroneous"); *Evans v. Mathis Funeral Home, Inc.*, 996 F.2d 266, 268 (11th Cir. 1993) (same); *Adams v. Sewell*, 946 F.2d 757, 768 (11th Cir. 1991) ("The district court is afforded great discretion in ruling on the admissibility of expert testimony, and we will reverse only for a clear abuse of that discretion").

D.C. Circuit — The D.C. Circuit describes the standard of review as "abuse of discretion." *United States v. Boney*, *supra*, 977 F.2d 624 at 628; *Joy v. Bell Helicopter Textron, Inc.*, 999 F.2d 549, 567 (D.C. Cir. 1993). However, the court has acknowledged that "[o]ther circuits have stated that a district court's admission of expert testimony will be overturned only if manifestly erroneous," and that "[w]e understand these circuits to be applying the same test that we apply here." *Boney*, 977 F.2d at 628 n.2.

Federal Circuit — *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1409 n.2 (Fed. Cir. 1994) ("decision to allow expert testimony is within the discretion of the trial court and will not be disturbed absent an abuse of such discretion"); *Milmark Servs., Inc. v. United States*, 731 F.2d 855, 860 (Fed. Cir. 1984) ("Since the admissibility of expert testimony is within the discretion of the trial judge, this action is to be sustained unless manifestly erroneous.").

Thus, all circuits employ the "abuse of discretion" standard for review of district court decisions regarding expert testimony, sometimes referring to it using the older, "manifestly erroneous" language. Further, there appears to be unanimity that the differences are *only* ones of terminology and not of substance; we have located no decisions suggesting that there is any practical difference in the review that is conducted under these two labels. Nor have petitioners found any such decisions. They cite only one case in support of their argument that "[t]he issue . . . 'is important.'" Pet. at 13 (quoting *Mars v. United States*, 25 F.3d 1383, 1384 (7th Cir. 1994)). But the *Mars* decision is talking about a *different* issue. *Mars* offered some tentative observations about whether *de novo* review might apply where "the reliability of an entire *class* of scientific evidence depends on considerations that transcend the individual case," for example, expert testimony involving polygraph machines. *Id.* at 1384. That does seem like an important issue, and in *Mars* Chief Judge Posner was able to cite appellate court holdings on the issue going both ways (something sorely lacking in the petition). But this issue has nothing to do with the question in the petition.

Thus, all that petitioners are left with is their criticism of a short discussion of the abuse-of-discretion standard (two pages out of an 80-page decision) in the Third Circuit's decision two years ago in *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 749-50 (3d Cir. 1994), *cert. denied*, 115 S. Ct. 1253 (1995). Petitioners claim that this *Paoli* discussion, cited by the court of appeals below, is "extreme" and represents "quite a different standard of review" than that followed in all other circuits. Pet. at 6, 10.

The *Paoli* analysis of the nature of abuse-of-discretion review is in no way extreme. "There are a half dozen different definitions of 'abuse of discretion,'" which serves as "'a verbal coat of . . . many colors.'" Friendly, *supra*, 31 Emory L.J. at 763 (quoting *United States v. L.A. Tucker Truck Lines*, 344 U.S. 33, 39 (1952) (Frankfurter, J., dissenting)). As Judge Friendly explained in his seminal article on the subject,

> The justifications for committing decisions to the discretion of the trial court are not uniform, and may vary with the specific types of decisions. Although the standard of review in such instances is generally framed as 'abuse of discretion,' in fact the scope of review will be directly related to the reason why that category or type of decision is committed to the trial court's discretion in the first instance.

Id. at 764. *See, e.g., id.* at 760-61, 773-84. The *Paoli* decision simply applied this commonsense observation, about the contextual variations in the application of abuse-of-discretion review, to the particular context of district court factfinding on the admissibility of expert testimony. In so doing, the *Paoli* court articulated several reasons for closer scrutiny of at least some factfinding in this context. *See* 35 F.3d at 749-50. The concerns laid out in *Paoli* are ones that are unavoidably at play in appellate decisionmaking under the abuse-of-discretion review standard, but that often go unstated. The fact that the author of the *Paoli* decision would address them briefly in his lengthy and quite scholarly opinion is hardly surprising or extreme.

In any event, the *Paoli* commentary on the standard of review, which did not warrant a grant of certiorari two years ago, appears to have no doctrinal importance at this point in time. In *Paoli* itself, it is unclear whether this analysis had any concrete effect on the court's holdings, given that the Third Circuit ultimately went on to affirm the bulk of the district court's rulings. *See* 35 F.3d at 733-34, 752-95. Even in the Third Circuit, the *Paoli* analysis of the standard of review has not been cited since; instead, in every subsequent decision addressing evidentiary rulings the Third Circuit has simply stated that it reviews for abuse of discretion.[1]

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[1] *See Coalition v. State Bd. of Educ. of the State of Delaware*, 90 F.3d 752, 759 (3d Cir. 1996); *Duquesne Light Co. v. Westinghouse Elec. Corp.*, 66 F.3d 604, 613 (3d Cir. 1995); *United States v. Velasquez*, 64 F.3d 844, 847-48 (3d Cir. 1995); *Sanes, supra*, 57 F.3d at 340-41; *Affiliated Mfrs., Inc. v. Alcoa*, 56 F.3d 521, 525-26 (3d Cir. 1995); *United States v. Brink*, 39 F.3d 419, 427 (3d Cir. 1994); *Habecker v. Clark Equip. Co.*, 36 F.3d 278, 289-90 (3d Cir. 1994), *cert. denied*, 115 S. Ct. 1313 (1995).

Likewise, since the brief mention of *Paoli* in the decision below, the Eleventh Circuit has ignored the point and has simply engaged in abuse-of-discretion review, without special elaboration. *See Harris v. Chapman*, 1996 U.S. App. LEXIS 26607, at *13 (11th Cir. Oct. 11, 1996) ("We review the district court's evidentiary rulings for abuse of discretion."); *United States v. Paradies*, 1996 U.S. App. LEXIS 24902, at *70-*71 (11th Cir. Sept. 23, 1996) ("The district court's exclusion of expert testimony is subject to an abuse of discretion standard"). Nor has any other circuit addressed the *Paoli* analysis in a case where the issue of the standard of review would make any conceivable difference to the outcome.[2]

Thus, a review of the existing caselaw on the standard of review for district court evidentiary factfinding reveals that all the circuits are in broad agreement. The "abuse of discretion" standard, sometimes called the "manifestly erroneous" standard, applies everywhere, even in the Third Circuit and the Eleventh Circuit. The two pages of *Paoli* that are emphasized by petitioners have not been relied on to support a holding in *any* subsequent federal

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[2] In a supplemental brief, petitioners have emphasized the decision of the Tenth Circuit in *Duffee v. Murray Ohio Mfg. Co.*, 91 F.3d 1410 (10th Cir. 1996). However, *Dufee*'s discussion of the *Paoli* analysis, like the mention of *Paoli* in the decision of the Eleventh Circuit in this case, is plainly dicta because on the record in that case the district court would have been affirmed regardless of the standard of review. *See Duffee v. Murray Ohio Mfg. Co.*, 879 F. Supp. 1078, 1081, 1086 (D. Kan. 1995) (expert "did not use a methodology comparable to that used by a bicycle designer in arriving at his conclusion that the particular bicycle was defectively designed in having only a rear coaster brake system"; indeed, the expert "practically conceded that he had reached his opinion without tracking the methodology or analysis that would be employed by a reasonable bicycle manufacturer or designer."). In failing to apply the *Paoli* analysis of abuse-of-discretion review, *Duffee* is no different than the seven Third Circuit decisions on this issue since *Paoli*, and the two Eleventh Circuit decisions on this issue since the decision below. See pp. 14-15 & n.1, *supra*. Since neither of the Seventh Circuit decisions cited by the Tenth Circuit addressed the *Paoli* analysis, either, *see* 91 F.3d at 1411, *Duffee* simply provides a further illustration of the fact the *Paoli* analysis is currently of no doctrinal significance and has been effectively ignored both inside and outside the Third Circuit.

appellate decision, either inside or outside the Third Circuit. Indeed, this aspect of *Paoli* has not even been mentioned in the Third Circuit. It was mentioned in the decision below rendered six months ago, but only as an aside that made no difference to the judgment rendered. Since then, the *Paoli* analysis has been ignored in the Eleventh Circuit. Thus, even if one were to set aside the fact that the judgment below was rendered entirely on *de novo* review, there would still be no convincing rationale for granting certiorari to address the correctness of the two sentences in the Eleventh Circuit's opinion that are the basis of the petition.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,
v.
ROBERT K. JOINER, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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IN THE

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GENERAL ELECTRIC COMPANY, *et al.*,
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REPLY TO BRIEF IN OPPOSITION

1. Respondents assert that the District Court was so clearly wrong to exclude these scientific opinions that it would be reversed under any standard of review. Br. Opp. 1, 6. But the dissenting judge did not think so. The dissent emphatically concluded that the District Court had acted well within ordinary discretion and common sense in not allowing unsupported opinions that "leap to the conclusion" "with blue smoke and sleight of hand." P.C.A. 22a. The trial court did not abuse its discretion, the dissent believed, by excluding conclusions with no scientific evidence to support them, *id.* at 23a-24a, 28a, and in declining to allow "blind faith" to fill "the analytical gap," *id.* at 27a.

Respondents alternatively offer a revisionist explanation of the Eleventh Circuit's decision. The Court of Appeals, they say, so completely reexamined and rejected the District Court's ruling that the decision really amounted to *de novo* review. Br. Opp. 1, 7. But a *de novo* standard to review a trial court's application of *Daubert* to particular facts would be totally at variance with the standard of other Circuits. If as respondents argue the Eleventh

Circuit really went even beyond the "particularly stringent" standard it announced, P.C.A. 4a, then that would be all the more reason to grant certiorari.[1]

What matters is that the Eleventh Circuit, just as it stated, reviewed the District Court's *Daubert* exclusions under a different standard, one far less deferential than is accorded *Daubert* rulings in any other Circuit except the Third. Just as it said, the Court of Appeals here reviewed in "particularly stringent" detail the District Court's conclusions as to whether the bases of the opinions met the *Daubert* standards. The Court of Appeals reexamined the proffered opinions and the bases they cited and reached its own conclusions. See P.C.A. 8a-16a. In doing so it made its own judgments about matters a district court is better equipped to decide—"multifarious, fleeting, special, narrow facts that utterly resist generalization." *Koon* v. *United States*, 116 S. Ct. 2035, 2047 (1996), quoting *Cooter & Gell* v. *Hartmarx Corp.*, 496 U.S. 384, 404 (1990), and *Pierce* v. *Underwood*, 487 U.S. 552, 561-62 (1988). Such judgments "involve fact-intensive, close calls." *Cooter & Gell*, *supra*, 496 U.S. at 404.

[1] Respondents in their appeal indeed sought to label virtually every part of the District Court's findings with which they disagreed as an error of legal interpretation, subject to *de novo* review. But they also argued that "if a district court uses a proper construction of the Federal Rules of Evidence in ruling on admissibility issues, its rulings are subject to abuse-of-discretion review" and that "abuse-of-discretion review is conducted *more strictly, and with greater scrutiny*, where necessary to ensure that the district court does not substitute its judgment for that of a jury." Reply Brief of Appellants, No. 94-9131, 11th Cir., at 6 n.3 (emphasis supplied). Although respondents tell this Court that "[o]n appeal, Joiner did not attack any exercise of the district court's discretion," Br. Opp. 3, they told the Court of Appeals that "on this record it would be an abuse of discretion not to admit the testimony of Joiner's experts," and that the District Court "erred as a matter of law in ruling the testimony of Joiner's experts inadmissible on the ground that the experts' opinions 'do not fit the facts in this case.'" Brief of Appellants, No. 94-9131, 11th Cir., at 6, 22.

The standard altered the result. For just one example, the Eleventh Circuit reversed the District Court in part for determining that the experts' proffered conclusions were not supported by scientific studies and did not fit the facts of the case. P.C.A. 12a-13a. But at least two Circuits (which apply the "manifestly erroneous" standard) have instructed their district courts that examining experts' conclusions is not cause for reversal, but rather an essential step in applying *Daubert* to determine whether experts' opinions have a basis in science and fit the issues in dispute. See *Lust* v. *Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 598 (9th Cir. 1996); *Claar* v. *Burlington N.R.R.*, 29 F.3d 499, 501 (9th Cir. 1994); *O'Conner* v. *Commonwealth Edison Co.*, 13 F.3d 1090, 1106-07 (7th Cir.), *cert. denied*, 114 S. Ct. 2711 (1994). For another example, the Eleventh Circuit, applying its standard, reversed the District Court's conclusion, A. 58a-62a, that two preliminary animal studies did not fit or provide basis in science for claiming causation of the human disease in the case before it. P.C.A. 11a-12a. Yet other Circuits hold that it is not an abuse of discretion to exclude under *Daubert* expert opinions that rely heavily on animal studies. *E.g.*, *Lust* v. *Merrell Dow*, *supra*, 89 F.3d at 597. See also P.C.A. 25a-27a.[2]

2. Respondents evade the central issue. For page after page they seek to demonstrate that the standard of "manifestly erroneous" used in six Circuits is not much different from "abuse of discretion" used in four others. Br. Opp. 8-13.[3] But that is not what this petition is about.

[2] Respondents' procedural summary of the District Court's decision appears designed to confuse. Respondents say that the District Court granted summary judgment based on insufficient evidence of exposure, and then "[a]s a second ground" excluded expert testimony under Rule 702, Fed. R. Evid. Br. Opp. 3. What the District Court in fact did, as the Court of Appeals recognized, was to hold that the proffered expert opinions did not satisfy Rule 702; that *Daubert* exclusion left no evidence to avert summary judgment—the *Paoli* situation. See P.C.A. 68a.

[3] Even on that peripheral question, it is puzzling that respondents cite cases that for the most part were decided *before*, and so neces-

For even if one assumed, *arguendo*, that the ten Circuits that use "manifestly erroneous" or "abuse of discretion" were of one mind, that still leaves the Eleventh and Third Circuits off by themselves, applying instead their "particularly stringent" standard of review, P.C.A. 4a, whenever an exclusion under *Daubert* results in summary judgment. The "widespread agreement among the circuits" that respondents perceive, Br. Opp. 8, is a widespread agreement that the standard of review applied by the Eleventh and Third Circuits to *Daubert* exclusions is wrong.[4]

3. One searches through fifteen pages of respondents' brief before finding mention of *Duffee* v. *Murray Ohio Mfg. Co.*, 91 F.3d 1410 (10th Cir. 1996) (see petitioners' Supplemental Brief), buried in a terminal footnote. Br. Opp. 15 n.2. The Tenth Circuit in *Duffee* certainly did not think that the present case and *Paoli* were applying the same standard of review as the other Circuits, or that it made no difference. The Tenth Circuit—citing this very case—pointed out that as to standard of review of *Daubert* exclusions, the Circuits are split, with the Eleventh and Third Circuits arrayed on one side, and all the other numbered federal Circuits disagreeing with them. 91 F.3d at 1411.

What respondents say when they finally acknowledge *Duffee* is peculiar. They say it is "plainly dicta," Br. Opp. 15 n.2—even though the *Duffee* court called standard of review "[t]he only issue that this court must reach." 91 F.3d at 1410. Respondents also say that "in failing to follow the *Paoli* analysis" *Duffee* resembles many other decisions. Br. Opp. 15 n.2. Indeed it does, because the *Paoli* standard is the law in only two Circuits.

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sarily did not address, *Daubert*. See Br. Opp. 9-12. For example, respondents quote at great length, Br. Opp. 9, *United States* v. *Rahm*, 993 F.2d 1405 (9th Cir. 1993), which was decided prior to *Daubert* and more than a year before *Paoli*.

[4] Respondents' startling statement to this Court that "appellate court holdings going both ways" are "sorely lacking in the petition," Br. Opp. 13, is inexplicable unless they failed to read pages 6 through 11 of the petition.

4. Respondents argue that the standard of appellate review is just words, mere "terminology," "boilerplate" that is "minor" and doesn't affect outcomes. Br. Opp. i, 1, 8, 14. The real "concerns" by which appellate judges decide cases, respondents explain, "often go unstated." Br. Opp. 14. But appellate judges themselves certainly have not shared respondents' view that the standard of appellate review is a trivial or superficial matter.[5] Neither has this Court. Just five years ago, this Court emphatically rejected essentially the same dismissive argument plaintiffs now try to revive:

> "We decline the invitation to assume that courts of appeals craft their opinions disingenuously. . . .
>
> "Nor does it suffice to recognize that little substantive difference may separate the form of deference articulated and applied by the several Courts of Appeals and the independent appellate review urged by petitioner. . . .
>
> ". . . We do not doubt that in many cases the application of a rule of deference in lieu of independent review will not affect the outcome of an appeal. . . .
>
> ". . . These few instances, however, make firm our conviction that the difference between a rule of deference and the duty to exercise independent review is 'much more than a mere matter of degree.' "

Salve Regina College v. *Russell*, 499 U.S. 225, 236-38 (1991), quoting *Bose Corp.* v. *Consumers Union of United States, Inc.*, 466 U.S. 485, 501 (1984). Accordingly, certiorari has been granted many times to resolve circuit splits over the standard of appellate review. See, *e.g.*, *Koon* v. *United States*, 116 S. Ct. 2035, 2043

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[5] See, *e.g.*, *United States* v. *Conley*, 4 F.3d 1200, 1204 (3d Cir. 1993) ("the standard of review can be outcome determinative"), *cert. denied*, 510 U.S. 1177 (1994); *United States* v. *Vontsteen*, 950 F.2d 1086, 1091 (5th Cir.) ("the standard chosen often affects the outcome of the case"), *cert. denied*, 505 U.S. 1223 (1992); *Jackson* v. *Harvard University*, 900 F.2d 464, 466 (1st Cir.) ("the standard of review is crucial"), *cert. denied*, 498 U.S. 848 (1990); *Fox* v. *Commissioner*, 718 F.2d 251, 253 (7th Cir. 1983) ("[t]he critical issue in this case is . . . our standard of review").

(1996); *Ornelas* v. *United States*, 116 S. Ct. 1657, 1661 (1996); *Wilton* v. *Seven Falls Co.*, 115 S. Ct. 2137, 2139 (1995).[6]

Further trying to minimize the issue, respondents repeatedly say the circuit split concerns merely "two sentences." See Br. Opp. 1, 6, 8, 15. Those two sentences, however, are the ones that state the standard of review that the Court of Appeals used to reverse the District Court. P.C.A. 4a. Not many words are required for a court of appeals to state the standard of review it is using —particularly when, as here, the Eleventh Circuit also specifically cited and incorporated by page reference the lengthier analysis and exposition by the Third Circuit in *Paoli*. See P.C.A. 4a-5a.[7] Certainly this Court has never demanded court-of-appeals verbosity as a condition for certiorari.[8] If standard of review were really as incon-

[6] Even respondents' secondary references are quite misleading. What Justice Frankfurter actually said in the dissenting sentence incompletely quoted at Br. Opp. 1 was: "I do not use the term '*jurisdiction*' because it is a verbal coat of too many colors." *United States* v. *L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 39 (1952) (Frankfurter, J., dissenting) (emphasis supplied). He was not talking about abuse of discretion at all. Judge Friendly in a 1982 lecture later picked up the phrase as descriptive of "abuse of discretion" as well. Friendly, *Indiscretion About Discretion*, 31 EMORY L.J. 747, 768 (1982). But in saying that, Judge Friendly was underscoring exactly the point that petitioners make here: that the standard of review *does* matter, that a phrase like "abuse of discretion" may conceal fundamentally different standards, and that "[t]he main thrust of this lecture is that there is not just one standard of 'abuse of discretion' on the part of the trial judge." *Id.* at 783. It is ironic that respondents cite Judge Friendly, who wanted more attention paid to standards of appellate review, as support for ignoring the kind of differences he was attempting to illuminate.

[7] The discussion in *Paoli* has been called "the most thorough, albeit controversial, judicial analysis of the standard of review issue." Note, *Developments in the Law—Confronting the New Challenges of Scientific Evidence*, 108 HARV. L. REV. 1481, 1528 (1995), but also "without authority or precedent." Wiseman, *Judging the Expert*, 55 OHIO ST. L.J. 1105, 1112 (1994).

[8] This Court of course regularly grants certiorari to review decisions in which courts of appeals have written less than two

sequential as respondents say, one wonders why the Tenth Circuit in *Duffee*, citing the present case, said that "[t]he only issue that this court must reach is the question of which standard should be used to review decisions to exclude expert testimony under *Daubert* that result in summary judgment." 91 F.3d at 1410-11.

5. The last two paragraphs of respondents' brief—the only ones that finally address the petition—consist of a succession of misstatements. It is extraordinary, for example, that respondents assert to this Court that *Paoli* has "not been relied on to support a holding in *any* subsequent federal appellate decision," "has been effectively ignored inside and outside the Third Circuit," and "is currently of no doctrinal significance and has been effectively ignored." Br. Opp. 15-16 and 15 n.2 (emphasis in original). In the very case before this Court, the standard of *Paoli* was explicitly adopted by another Circuit, the Eleventh. (Respondents call that "an aside." Br. Opp. 16.) And three months ago *Paoli* was quoted and explained by yet another Circuit, the Tenth—which after consideration rejected it. *Duffee, supra*, 91 F.3d at 1411. Legal commentators have written about and questioned the *Paoli* holding and pointed out the need for a definitive resolution of the scope of appellate review under *Daubert*.[9] Of course opinions following the rule of the present case and *Paoli* are not found in other Circuits—the other Circuits disagree with it. But this Court frequently grants certiorari when only one Circuit has deviated from the others, and here on an important and constantly arising issue two have done so.

sentences, or nothing at all. *E.g.*, *Stutson* v. *United States*, 116 S. Ct. 600, 602 (1996); *Williamson* v. *United States*, 114 S. Ct. 2431, 2434 (1994); *Howlett* v. *Birkdale Shipping Co.*, 114 S. Ct. 2057, 2062 (1994).

[9] Wiseman, *supra* n. 7; Note, *Developments in the Law*, *supra* n. 7, at 1527-29; see also Fenner, *The Daubert Handbook: The Case, Its Essential Dilemma, and Its Progeny*, 29 CREIGHTON L. REV. 939, 1030 (1996) ("The non-*Paoli* cases seem to be correct").

Respondents have no basis whatsoever to say to this Court that "all [*sic*] the courts are in broad agreement," Br. Opp. 15, or that *Paoli* does not govern in the Third Circuit. They collect in a footnote seven cases they describe opaquely as Third Circuit "decision[s] addressing evidentiary rulings." Br. Opp. 14. What respondents fail to advise the Court is that none of the cases they cite involved "evidentiary rulings" of the kind reviewed in *Paoli* and here: exclusions of scientific evidence under *Daubert* resulting in summary judgment.[10] Similarly, two recent Eleventh Circuit cases respondents cite, Br. Opp. 15, likewise have nothing at all to do with *Daubert* and the issue here.[11]

6. The standard of appellate review goes right to the heart of whether *Daubert* will have real meaning. This Court in *Daubert* emphasized that in deciding whether to admit or exclude scientific opinions, district courts are to exercise a "gatekeeping role." 509 U.S. at 597. But what the Third Circuit held in *Paoli*, and the Eleventh Circuit held here, is that the standard of review should be different—and "particularly stringent," P.C.A. 4a—whenever the gatekeeper bars the gate to unsupported scientific opinions, instead of leaving it open. Today in the Third

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[10] *Coalition To Save Our Children* v. *State Bd. of Educ.*, 90 F.3d 752 (3d Cir. 1996), and *Duquesne Light Co.* v. *Westinghouse Elec. Corp.*, 66 F.3d 604 (3d Cir. 1995), were exclusions not based on *Daubert*. *Affiliated Mfrs., Inc.* v. *Aluminum Co.*, 56 F.3d 521 (3d Cir. 1995), did not involve any expert issue at all. And the other four cases cited by respondents in their footnote involved *Daubert* rulings *at trial*; the "particularly stringent" or "hard look" standard of the present case and *Paoli* does not reach that situation, instead applying to pretrial exclusions under *Daubert* that result in summary judgment.

[11] *Harris* v. *Chapman*, 1996 U.S. App. Lexis 26607 (11th Cir. 1996), affirmed *admission* of testimony from a fact witness who "stated no 'opinion,' let alone an expert one." *Id.* at *14. *United States* v. *Paradies*, 1996 U.S. App. Lexis 24902 (11th Cir. 1996), affirmed exclusion of testimony on law from a former Chief Justice of Georgia presented as a "legal expert."

and Eleventh Circuits district judges face a more hostile review and a more likely reversal if they exclude testimony purportedly based on science than if they let it in. Such a tilt has no support in Rule 702 and is contrary to the teaching of *Daubert*. It is also contrary to this Court's holdings, in many contexts, that have rejected skewed rules that would apply one standard if a decision under review came out one way, but a stricter one if it came out the other. See, *e.g.*, *First Options of Chicago, Inc.* v. *Kaplan*, 115 S. Ct. 1920, 1926 (1995) ("the reviewing attitude that a court of appeals takes toward a district court decision should depend . . . not upon what standard of review will more likely produce a particular substantive result"); *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986); *Calder* v. *Jones*, 465 U.S. 783, 790-91 (1984).

7. Since the petition for certiorari was filed, the other courts of appeals have continued to reject the standard followed by the Eleventh and Third Circuits. See *Cummins* v. *Lyle Industries*, 93 F.3d 362, 367 (7th Cir. Aug. 16, 1996) ("we will not disturb the district court's findings unless they are manifestly erroneous"); *Coury* v. *Road & Driveway Co.*, 1996 U.S. App. Lexis 26223 at *2 (9th Cir. Oct. 2, 1996) ("we will uphold the court's decision to exclude expert testimony unless it is 'manifestly erroneous' "); *Peitzmeier* v. *Hennessy Industries, Inc.*, 1996 U.S. App. Lexis 26115 at *6 (8th Cir. Oct. 4, 1996) ("Decisions concerning the admission of expert testimony lie within the broad discretion of the trial court, and these decisions will not be disturbed on appeal absent an abuse of that discretion"). And a month ago, the Fifth Circuit specifically declined to hold that the standard of appellate review should be more stringent when exclusion of expert testimony results in summary judgment:

> "The admissibility of expert testimony is governed by the same rules, whether at trial or on summary judgment. And we review the decision of the trial court by the same abuse of discretion standard."

First United Fin. Corp. v. *United States Fidelity & Guar. Co.*, 96 F.3d 135, 136-37 (5th Cir. 1996).

CONCLUSION

For the reasons stated herein and previously, certiorari should be granted.

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November 5, 1996

(2)

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,
v.
ROBERT K. JOINER, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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IN THE

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Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

---

SUPPLEMENTAL BRIEF FOR PETITIONERS

Pursuant to Rule 15.8 of the Rules of this Court, petitioners respectfully draw to this Court's attention the decision of the United States Court of Appeals for the Tenth Circuit in *Duffee* v. *Murray Ohio Mfg. Co.*, Nos. 95-3055 and 95-3241, issued August 5, 1996. The Tenth Circuit decided *Duffee* the same day that the petition for certiorari in this case was filed.

In this new decision, the Tenth Circuit confirms the split in the Circuits and specifically rejects the holding of the Eleventh Circuit in the present case. The Tenth Circuit explains:

"The only issue that this court must reach is the question of what standard should be used to review decisions to exclude expert testimony under *Daubert* that result in summary judgment. . . . The Third and Eleventh Circuits, while acknowledging that evidentiary rulings usually receive greater deference, have nonetheless held that 'when the district court's exclusionary evidentiary rulings with respect to scientific expert testimony will result in a summary or directed judgment, we will give them a "hard look" (more stringent review) to determine if a district court has abused its discretion in excluding evidence as unreliable.' *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749-750 (3d Cir. 1994) (citation omitted); see *Joiner* v. *General Elec. Co.*, 78 F.3d 524, 529 (11th Cir. 1996) (applying 'a particularly stringent standard of review to the trial judge's exclusion of expert testimony.') The Seventh Circuit, on the other hand, has held that the trial judge's decision to exclude evidence under *Daubert* should be reviewed for abuse of discretion, even when that decision results in summary judgment. *Buckner* v. *Sam's Club, Inc.*, 75 F.3d 316, 318 (7th Cir. 1996); see *Rosen* v. *Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996)."

Pp. 2a-3a, *infra*. The Tenth Circuit then explicitly rejects the standard of the Eleventh and Third Circuits, and follows that of the Seventh Circuit: it concludes that rulings excluding expert testimony under *Daubert* "are properly reviewed under the traditional abuse of discretion standard." P. 3a, *infra*.

The full text of the Tenth Circuit's decision, rejecting that of the Eleventh Circuit here, is reprinted in the addendum hereto.

CONCLUSION

Certiorari should be granted.

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September 12, 1996

ADDENDUM

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

Nos. 95-3055 and 95-3241

SHANE DUFFEE, Minor, by and
Through Guardian and Next Friend,
ROSE THORNTON,
Plaintiff-Appellant,

v.

MURRAY OHIO MANUFACTURING CO.,
WAL-MART STORES, INC., and
SHIMANO AMERICAN, INC.,
Defendants-Appellees.

Appeal from the United States District Court
for the District of Kansas
(D. Ct. No. 94-CV-4022)
Judge Sam A. Crow

August 5, 1996, Filed

Before TACHA, McWILLIAMS, and BALDOCK, Circuit Judges.

TACHA, Circuit Judge.

On February 21, 1992, Shane Duffee was struck by a car while riding his bicycle. By and through his guardian and next friend Rose Thornton, Duffee sued Wal-Mart, Murray Ohio Manufacturing Company, and Shimano American, Inc., alleging warning, design, and manufacturing defects under negligence, strict liability, and warranty theories. The district court granted summary judgment in favor of Wal-Mart and Murray on all claims on February 8, 1995. The court granted summary judgment in favor of Shimano on all claims on July 24, 1995. After careful review of the record, we adopt the analysis of the district court's February 8, 1995, and July 24, 1995, orders.

In the February 8 order, the district court determined that testimony from Duffee's expert regarding the safety of the brakes on Duffee's bike was inadmissible under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). The only issue that this court must reach is the question of which standard should be used to review decisions to exclude expert testimony under *Daubert* that result in summary judgment. Ordinarily we review the grant or denial of summary judgment de novo. *Wolf v. Prudential Ins. Co. of Am.*, 50 F.3d 793, 796 (10th Cir. 1995). Evidentiary rulings, however, are generally reviewed for abuse of discretion. *Hinds v. General Motors Corp.*, 988 F.2d 1039, 1047 (10th Cir. 1993). The Third and Eleventh Circuits, while acknowledging that evidentiary rulings usually receive greater deference, have nonetheless held that "when the district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment, we will give them a 'hard look' (more stringent review) to determine if a district court has abused its discretion in excluding evidence as unreliable." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749-50 (3d Cir. 1994) (citation omitted); see *Joiner v. General Elec. Co.*, 78 F.3d 524,

529 (11th Cir. 1966) (applying "a particular stringent standard of review to the trial judge's exclusion of expert testimony.") The Seventh Circuit, on the other hand, has held that the trial judge's decision to exclude evidence under *Daubert* should be reviewed for abuse of discretion, even when that decision results in summary judgment. *Buckner v. Sam's Club, Inc.*, 75 F.3d 290, 292-93 (7th Cir. 1996); see *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996). *Daubert* requires district judges to act as gatekeepers to ensure that scientific evidence is both relevant and reliable. *Daubert*, 113 S. Ct. at 2796-97. This entails two inquiries: whether the reasoning and methodology underlying the testimony is scientifically valid, and whether the reasoning and methodology can properly be applied to the facts. Id. at 2796. Like the Supreme Court, we "are confident that federal judges possess the capacity to undertake this review." Id. Their decisions, therefore, are properly reviewed under the traditional abuse of discretion standard. In this case, the district judge found that the testimony of the plaintiff's expert was not supported by appropriate validation, and therefore was inadmissible under *Daubert*. After reviewing the record, we conclude that the district judge did not abuse his discretion by excluding this testimony.

We AFFIRM for substantially the reasons given by the district court and ORDER both of the district court's orders in this case to be published.

(6)

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,

v.

ROBERT K. JOINER, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

---

SECOND SUPPLEMENTAL BRIEF FOR PETITIONERS

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ROBERT K. JOINER, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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SECOND SUPPLEMENTAL BRIEF FOR PETITIONERS

Pursuant to Rule 15.8 of the Rules of this Court, petitioners respectfully draw to the Court's attention two new decisions by two courts of appeals that reject the standard of review adopted by the Eleventh Circuit in the present case.

1. In *Cavallo* v. *Star Enterprise*, Nos. 95-2540 and 95-2541, decided November 20, 1996, the Fourth Circuit explicitly disapproved the *Paoli* standard of "hard look" or "particularly stringent" review that the Eleventh Circuit explicitly approved here. The Fourth Circuit held:

> "But the parties disagree on the standard by which we review the district court's decision to exclude expert testimony. The Cavallos argue, quoting the Third Circuit's decision in *In re Paoli R.R. Yard PCB Litigation*, that trial judges should not be given

the same deference in their decisions to exclude expert evidence as they are given in their decisions about other types of evidence:

> The decision to exclude expert testimony resulting in a summary judgment is subject to a 'hard look' review by the appeals court, i.e., a less deferential review than the traditional abuse of discretion standard in light of 'a significant risk that district judges will set the threshold too high and will in fact force appellants to prove their case twice.'

Brief of Appellants at 3 (quoting 35 F.3d 717, 733 (3d Cir. 1994)). As the defendants point out, however, this court recently reached the opposite conclusion. In *Benedi* v. *McNeil-P.P.C., Inc.*, a Fourth Circuit panel stated that '*Daubert* [v. *Merrell Dow Pharmaceuticals, Inc.*,] clearly vests the district courts with discretion to determine the admissibility of expert testimony.' 66 F.3d 1378, 1384 (4th Cir. 1995) (citing 113 S. Ct. 2786 (1993)). Accordingly, we review the district court's decision only for abuse of discretion.

* * * *

> ". . . The Cavallos have shown that the question of admission is close, but we defer to the court's decision to exclude the evidence and affirm its summary judgment on Count I."

See pp. 5a-6a, 18a, *infra*.

2. In *Bogosian* v. *Mercedes-Benz of North America, Inc.*, No. 96-1287, decided November 21, 1996, the First Circuit reaffirmed that in reviewing *Daubert* exclusions "we will uphold the district court's ruling in this area unless it is 'manifestly erroneous.' *Salem* v. *United States Lines Co.*, 370 U.S. 31, 35 (1962)"—exactly as petitioners unsuccessfully argued here to the Eleventh Circuit *—

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* Petitioners argued that "[a]lthough the Eleventh Circuit has not issued an opinion concerning the admissibility of expert testimony since the Supreme Court's decision in *Daubert*, nothing in *Daubert* gives any hint that the standard of review embraced in *Salem* . . . should now be changed. On the contrary, since *Daubert* was decided, nearly all of the Circuits have addressed the standard of review and continue to adhere to the rule of *Salem*." Joint Brief of Defendants-Appellees, No. 94-9131, 11th Cir., at 9 (footnote omitted). Petitioners also pointed out in seeking *en banc* review that by following *Paoli* and rejecting *Salem*, "[t]he majority's opinion also conflicts with the decisions of eleven other federal circuits . . . ." Suggestion of Rehearing En Banc of Defendants-Appellees, No. 94-9131, 11th Cir., at 5.

and concluded that "we cannot say that it abused its substantial discretion when finding inadequate the premises of the proposed testimony," and "we do not find the district court's decision to exclude Davidson's testimony to be manifestly erroneous." See pp. 24a-25a, 31a, 33a, *infra*.

The full texts of the Fourth Circuit and First Circuit opinions are reproduced in the addendum hereto.

CONCLUSION

Certiorari should be granted.

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December 9, 1996

ADDENDUM

ADDENDUM

PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 95-2540

ARDITH CAVALLO,
Plaintiff-Appellant,

and

LAWRENCE CAVALLO,
Plaintiff,

v.

STAR ENTERPRISE; TEXACO REFINING AND MARKETING (EAST), INCORPORATED; SAUDI REFINING, INC.,
Defendants-Appellees.

No. 95-2541

LAWRENCE CAVALLO,
Plaintiff-Appellant,

and

ARDITH CAVALLO,
Plaintiff,

v.

STAR ENTERPRISE; TEXACO REFINING AND MARKETING (EAST), INCORPORATED; SAUDI REFINING, INC.,
Defendants-Appellees.

Appeals from the United States District Court
for the Eastern District of Virginia, at Alexandria.
T. S. Ellis, III, District Judge; Albert V. Bryan, Jr.,
Senior District Judge.
(CA-94-1499-A)

Argued: April 3, 1996
Decided: November 20, 1996

Before ERVIN, Circuit Judge, LAY, Senior Circuit Judge of the United States Court of Appeals for the Eighth Circuit, sitting by designation, and TRAXLER, United States District Judge for the District of South Carolina, sitting by designation.

OPINION

ERVIN, Circuit Judge:

Ardith and Lawrence Cavallo sued Star Enterprise,[1] which operates a petroleum distribution terminal located near their home, alleging various damages from an underground petroleum release in 1990 and a fuel spill in 1991. Their complaint included four causes of action: Count I—"Negligence with Respect to AVJet Fuel Spill"; Count II—"Negligent Petroleum Release and Negligent Abatement and Remediation of the Petroleum Release"; Count III—"Common Law Trespass"; and Count IV—"Liability Under the State Water Control Law." The district court dismissed Counts II, III, and V under Fed. R. Civ. P. 12(b)(6), holding that they were barred by statutes of limitation and federal preemption. After discovery, the court granted Star's motion for summary judgment on Count I.

The Cavallos appeal. They contend that the district court applied an incorrect statute of limitation, misconstrued federal preemption doctrine, and erred in excluding the testimony of two of their experts.[2] We agree with

[1] Star Enterprise is a joint venture partnership between Texaco Refining and Marketing (EAST), Inc., and Saudi Refining, Inc. We refer to the defendants collectively as "Star."

[2] In addition to the questions they raise in their opening brief, the Cavallos add two new arguments in their Reply Brief: (1) that the statute of limitation applicable to their trespass and statutory claims is five years rather than two years, and (2) that "[t]he district court erred by failing to convert Star's Rule 12(b)(6) motion into a motion for summary judgment and by taking judicial notice of incomplete documents." The Cavallos abandoned the statute of limitation issue at oral argument, stating that they were not appealing it but might ask the district court to reconsider the question if we remand. Also at oral argument, the Cavallos noted that they had raised the conversion issue before the district court.

Under the decisions of this and the majority of circuits, an issue first argued in a reply brief is not properly before a court of appeals. *See Hunt v. Nuth*, 57 F.3d 1327, 1338 (4th Cir. 1995) (citing *United States v. Caicedo-Llanos*, 960 F.2d 158, 164 (D.C. Cir. 1992)), *cert. denied*, 116 S. Ct. 724 (1996); 9 James Wm. Moore, *Moore's Federal Practice* ¶ 228.02[2-3] (1995) ("The case law is to the effect that the appellant cannot raise new issues in a reply brief . . . ."). That the question was raised in the district court is immaterial. The Cavallos' omission of the issue from their initial brief denied Star an opportunity to respond, so considering it now "would be unfair to the appellee and would risk an improvident or ill-advised opinion on the legal issues raised." *Hunt*, 57 F.3d at 1338.

the Cavallos that the Complaint and the EPA Orders provide insufficient information to determine whether their claims are preempted. Thus we reverse the court's dismissal of Count II, that portion of Count III containing the loss of use and enjoyment claim, and Count IV and remand for further proceedings. We uphold the dismissal of that portion of Count III containing the personal injury claim, however, even though the court rested its decision on preemption, because it fails to state a claim under Virginia law. And we affirm the court's summary judgment on Count I, finding that the district court acted within its discretion by excluding the expert testimony.

I

Star's distribution terminal ("the Tank Farm") is located in Fairfax, Virginia, less than a mile west of the Cavallos' home. It includes office and warehouse space, a truck loading rack, underground storage tanks holding up to forty thousand gallons, and above-ground storage

tanks holding over seventeen million gallons. Drainage on the site is controlled by a containment dike and an on-site pond—water from the former is pumped into the latter—and the pond's contents are treated and released into local creeks.

On September 14, 1990, Fairfax residents noticed an oil "sheen" on the surface of Crook Branch Creek. Star soon acknowledged that a large amount of aviation fuel, diesel fuel, and gasoline had leaked into the soil and groundwater. Investigation by the Virginia State Water Control Board revealed an underground "plume" of various fuels. Thereafter, at the Board's request, the Environmental Protection Agency ("EPA") assumed responsibility for the investigation pursuant to the Resource Conservation and Recovery Act ("RCRA") § 7003, 42 U.S.C. § 6973. The EPA and Star negotiated an Administrative Consent Order—subsequently superseded by an Administrative Order—which required Star to implement corrective measures under EPA supervision. In accordance with the Orders, the EPA assumed control of Star's remediation efforts on July 3, 1991.

Another significant spill occurred on December 9, 1991. A valve was left open, allegedly due to the negligence of one of Star's employees or agents, and thirty-four thousand gallons of aviation fuel were released. The spill, contained by the dike, remained on the Tank Farm grounds for two weeks.

On the evening of the 1991 spill, the Cavallos were exposed to fuel vapors in a parking lot about five hundred feet from the Tank Farm. Both noticed an oil-like odor, and Mrs. Cavallo allegedly experienced an immediate irritating reaction. She was treated by several doctors, including Dr. Joseph Bellanti, Director of Allergy-Immunology at Georgetown Medical Center. Dr. Bellanti testified that Mrs. Cavallo suffered from sinusitis, conjunctivitis, and pulmonary dysfunction. His testimony was complemented by that of Dr. David Monroe, a toxicologist,

who reported that the exposure caused Mrs. Cavallo to experience burning eyes, conjunctivitis, sinusitis, and throat irritation. In addition to their exposure on the night of the 1991 spill, the Cavallos claim that since that time they continually have been exposed in their home to vapors from the Tank Farm. Mrs. Cavallo alleges that she continues to suffer physical symptoms caused by her exposure to the vapors, and both Cavallos claim damage to their property.

II

We review *de novo* the district court's summary judgments and 12(b)(6) dismissals. *See, e.g., Schatz v. Rosenberg,* 943 F.2d 485, 489 (4th Cir. 1991) (Rule 12(b)(6) dismissal), *cert. denied sub nom., Schatz v. Weinberg and Green,* 112 S. Ct. 1475 (1992); *Goodman v. RTC,* 7 F.3d 1123, 1126 (4th Cir. 1993) (summary judgment). But the parties disagree on the standard by which we review the district court's decision to exclude expert testimony. The Cavallos argue, quoting the Third Circuit's decision in *In re Paoli R.R. Yard PCB Litigation,* that trial judges should not be given the same deference in their decisions to exclude expert evidence as they are given in their decisions about other types of evidence:

> The decision to exclude expert testimony resulting in a summary judgment is subject to a "hard look" review by the appeals court, i.e., a less deferential review than the traditional abuse of discretion standard in light of "a significant risk that district judges will set the threshold too high and will in fact force appellants to prove their case twice."

Brief of Appellants at 3 (quoting 35 F.3d 717, 733 (3d Cir. 1994)). As the defendants point out, however, this court recently reached the opposite conclusion. In *Benedi v. McNeil-P.P.C., Inc.,* a Fourth Circuit panel stated that *"Daubert* [*v. Merrell Dow Pharmaceuticals, Inc.,*] clearly vests the district courts with discretion to determine the admissibility of expert testimony." 66 F.3d

1378, 1384 (4th Cir. 1995) (citing 113 S. Ct. 2786 (1993)). Accordingly, we review the district court's decision only for abuse of discretion.

III

A

The district court dismissed Count III which contained both a personal injury claim by Mrs. Cavallo and a claim for the loss of the use and enjoyment of the Cavallo's real property resulting from exposure to vapors under the federal preemption doctrine. See complaint Para. 79. In addition to defending the court's preemption analysis, Star offers an alternative ground for upholding the district court's dismissal. Under Virginia law, it argues, the Cavallos must show physical impact on their property, and "wafting vapors . . . [are] insufficient as a matter of law." To support its position, Star cites another Fourth Circuit case involving the Tank Farm—*Adams v. Star Enterprise*, 51 F.3d 417, 422-25 (4th Cir. 1995).

The *Adams* plaintiffs, a group of landowners, sued for diminution of their property values and for health risks allegedly caused by their subdivision's proximity to an underground "plume" of petroleum products leaked from the Tank Farm. The landowners did not claim that the plume actually contaminated their soil, nor that they detected vapors from the leak on their property. The harm they alleged consisted of a stigma attached to their subdivision and a "*fear* of being exposed to toxic materials." *Id.* at 422 & n.5. The court held that the landowners' claims could not proceed, because Virginia law allowed recovery only if "the activity or condition complained of was actually *physically perceptible* from the plaintiff[s'] property." *Id.* at 422-23 (emphasis added).

Star argues that "wafting vapors" are not "physically perceptible" under *Adams*. We disagree. The context for the *Adams* court's focus on physical perception was its

discussion of *Foley v. Harris*, in which the Virginia Supreme Court allowed recovery against a defendant whose wrecked cars were visible from the plaintiffs' property. 286 S.E.2d 186, 190-91 (Va. 1982). The *Adams* court distinguished *Foley* because the *Foley* plaintiffs, unlike those in *Adams*, could sense the source of the offense from their own property. *Adams*, 51 F.3d at 422-23. Smell, like sight, certainly constitutes physical perception. And, although the Cavallos do not allege that they smelled the vapors, the physical symptoms Mrs. Cavallo suffered also might suffice. We conclude, based upon *Adams*, that the portion of Count III relating to the loss of use and enjoyment claim may be cognizable under Virginia law and that it was error to dismiss it under Fed. R. Civ. P. 12(b)(6) upon the alternative ground suggested by Star. Since the damage alleged in *Adams* was based simply upon a fear of future events and these allegations are much more direct, we hold that they are sufficient to sustain the loss of use and enjoyment portion of Count III under Virginia law.

We reach a different result, however, with reference to that portion of Count III asserting a personal injury claim by Mrs. Cavallo. The Virginia Supreme Court stated in *Foley* that "[t]he discomfort and annoyance [complained of] must . . . be significant and of a kind that would be suffered by a normal person in the community." *Foley*, 286 S.E.2d at 190, 191 (emphasis added), Mrs. Cavallo is not such a person; in fact, she alleges specifically that she is "highly susceptible" to petroleum vapors. Complaint ¶ 50. Hence, the personal injury portion of Count III is not cognizable under Virginia law and was properly dismissed.

B

An agreement between the parties treats all the Cavallos' claims as filed on December 8, 1993. The district court ruled that all counts but Count I are necessarily barred by the interaction of the statutes of limitation and

federal preemption, because: (1) the counts involve remediation efforts at the Tank Farm, (2) the statutes of limitation bar all claims based on events occurring before December 8, 1991, and (3) preemption bars all claims based on events occurring after September 1991, when the EPA took control of remediation efforts. Because we affirm on other grounds the district court's dismissal of the physical injury claim in Count III, *supra* part III.A, we limit our preemption analysis to Count II, the portion of Count II containing the loss of use and enjoyment claim, and Count IV only.

This court summarized the law of preemption in *Worm v. American Cyanamid Co.*:

> The principles of preemption resolve conflicts between federal and state law on the authority of Article VI of the Constitution, which provides:
>
> > This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.
>
> U.S. Const. Art. VI, § 2. From this Supremacy Clause flows the well-established principle that federal legislation, if enacted pursuant to the Congress' constitutionally delegated authority, can nullify conflicting state or local actions. *See, e.g., Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 210-11, 6 L.Ed. 23 (1824).
>
> Preemption may occur on two bases, the first of which turns on discovering the intent of Congress. Congress may expressly provide that federal law supplants state authority in a particular field or its intent to do so may be inferred from its regulating so pervasively in the field as not to leave sufficient vacancy within which any state can act. *See, e.g., Rice v.*

> *Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 1152, 91 L.Ed. 1447 (1947). But even absent an express or implied congressional intent to preempt state authority in a field, state law is nevertheless preempted by operation of law to the extent that it actually conflicts with federal law. *See Wisconsin Public Intervenor v. Mortier*, —— U.S. ——, 111 S.Ct. 2476, 2482, 115 L.Ed.2d 532 (1991); *Pacific Gas & Elec. Co. v. State Energy Resources Conserv. & Dev. Comm'n*, 461 U.S. 190, 204, 103 S.Ct. 1713, 1722, 75 L.Ed.2d 752 (1983).
>
> . . . When we address the question of whether state law actualy conflicts with federal law, we resolve the more specific inquiries of whether "it is impossible to comply with both state and federal law" or "whether the state law stands as an obstacle to the accomplishment of the full purposes and objectives" of federal law. *See Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248, 104 S.Ct. 615, 621, 78 L.Ed.2d 443 (1984).
>
> With these principles stated, we proceed to an examination of [the statute in question], first to determine if Congress intended by its enactment to supplant state authority in the field, and if not, whether state tort and warranty law conflicts with the federal regulatory scheme.

970 F.2d 1301, 1304-05 (4th Cir. 1992).

Two years after *Worm*, in *Feikema v. Texaco, Inc.*, 16 F.3d 1408 (4th Cir. 1994), this court addressed whether state-court relief would conflict with an EPA Consent Order. The *Feikema* plaintiffs sought damages and an injunction requiring

> excavation, treatment and replacement of contaminated soil to a specified depth and over a specified area; . . . "enhanced ground water extraction and bio-remediation to reduce the off-site contamination";

> and . . . construction of a "free phase hydrocarbon trench removal system across the water table."

Id. at 1416. Because the EPA Order in *Feikema* focused on a particular incident, and thus was not intended to supplant state authority in the entire field, the court applied only the second, actual-conflict prong of the *Worm* inquiry:

> [W]hen the EPA, acting within valid statutory authority of the RCRA and not arbitrarily, enters into a consent order, that order will also preempt conflicting state regulation, including a federal court order based on state common law. . . .
>
> . . . [T]he test for determining whether state law conflicts with federal law is whether "it is impossible to comply with both state and federal law" or whether "the state law stands as an obstacle to the accomplishment of the full purposes and objectives" of federal law.

Feikema, 16 F.3d at 1416 (quoting *Worm*, 970 F.2d at 1305) (emphasis added) (other citations omitted). Noting that the Consent Order "addresse[d] the same site and conditions covered by the homeowners' suit," the *Feikema* court determined that an injunction would conflict with the EPA's activities and thus was preempted. *Id.*

Regarding the damages claims, the *Feikema* court expressed greater reluctance to preempt state law. It quoted the Supreme Court's opinion in *Nader v. Allegheny Airlines, Inc.*:

> A common-law right, even absent a saving clause, is not to be abrogated "unless it be found that the pre-existing right is so repugnant to the statute that the survival of such right would in effect deprive the subsequent statute of its efficacy; in other words, render its provisions nugatory."

426 U.S. 290, 298 (1976) (quoting *Texas & Pacific R. Co. v. Abilene Cotton Oil Co.*, 204 U.S. 426, 437 (1907)),

quoted in Feikema, 16 F.3d at 1413. Moreover, the *Feikema* court found indications in RCRA's legislative history that some state causes of action should be permitted: "[W]hile Congress intended for the EPA to have broad authority to act in an imminent hazard situation, it also intended such action to complement other efforts and remedies." *Feikema*, 16 F.3d at 1415 (citing *Report of the Committee on Environment and Public Works*, S. Rep. No. 98-284, 98th Cong., 1st Sess. 56 (1983)). Because the Consent Order did not provide for damages payments to homeowners, the court found, awarding damages to the plaintiffs would not conflict with the Consent Order. Consequently, it allowed the damages claims to proceed. *Id.* at 1417-18.

Judge Murnaghan wrote separately in *Feikema* to emphasize that the court was not applying a different standard to damages than to equitable relief. *Id.* at 1418 (Murnaghan, J., concurring). He stressed that, whatever the relief sought, a "claim is preempted *only* to the extent that it may actually conflict with the EPA's Consent Order and *only* while that Order remains in effect." *Id.* (Murnaghan, J., concurring). In *Feikema*, he wrote, preemption applied to the injunction claim but not the damages claims because, on the particular facts of the case, an injunction would conflict with the Consent Order but a damages award would not. *Id.* (Murnaghan, J., concurring).

The EPA Orders in this case, like those in *Feikema*, do not contemplate compensation for damages to private parties. Thus the Cavallos contend that the damages they seek, like the award sought in *Feikema*, would not conflict with the EPA Orders. The district court disagreed with the Cavallos, relying on Judge Murnaghan's concurrence, and held that the Orders preempted any damages claims based on remediation efforts within the scope of the Orders:

> [D]amages claims are preempted insofar as they arise from remediation efforts under the scope of the EPA Orders. The damages sought here distinguish the

> case from those damages which were allowed in *Feikema*. Damage liability for activities in conformity with the EPA Orders *conflicts* with the federal interest as effectively as an injunction.

Memorandum Opinion and Order at 5, *in* Joint Appendix at 197 (citing 16 F.3d 1408, 1418 (4th Cir. 1994) (Murnaghan, J., concurring)).

The district court used the correct "conflict" test, and we agree that Star cannot be held liable "for activities *in conformity with* the EPA Orders." But that does not end the inquiry, as the district court appears to have assumed. Although all of Star's allegedly tortious acts occurred after the EPA took control of remediation, the EPA Orders encompassed only remediation efforts, and all of Star's activities at the Tank Farm did not involve remediation. Moreover, even EPA-directed remediation efforts might be actionable if improperly performed. To determine whether damages would conflict with the EPA Orders, then, we must look beyond the temporal scope of the Orders and the scope of the activities they encompassed. Damages claims conflict with EPA Orders only if the allegedly tortious activities (1) were required, directed, or supervised by the EPA, and (2) were performed properly.

In Count II, the Cavallos allege "negligence, carelessness and recklessness" by Star in:

> a. Improperly operating, supervising, and/or maning the [Tank Farm] Facility;
>
> b. Improperly designing, installing and repairing and updating of the Facility;
>
> c. Failure to properly test and inspect Facility equipment;
>
> d. Failure to properly and promptly notify Plaintiff and Mantua residents of the Petroleum releases at the Facility[;]

> e. Failure to properly and promptly remediate [sic] and recover/remove the Petroleum Releases[;] and
>
> f. Failure to properly mitigate venting of storage tanks.

Complaint ¶ 72, *in* Joint Appendix at 38. Count IV is based in part on the December 1991 spill, and in part on Star's regular venting of its tanks. Complaint ¶¶ 86-87, *in* Joint Appendix at 21.

To the extent they occurred after December 8, 1991,[8] incidents of improper operation, supervision, management, design, installation, repair, and updating of the Tank Farm or its equipment may be actionable if not compelled by the EPA Orders. Likewise, failure by Star to notify the Cavallos of petroleum releases may support their claims if the releases or failures to notify were not authorized or approved by the EPA. For example, the Complaint indicates that the December 10, 1991, AVJet spill was a mistake—not contemplated by EPA Orders or officials—and alleges that Star waited eight days before notifying the EPA. Complaint ¶¶ 26-43, *in* Joint Appendix at 28-31. Damages caused by that spill, or by Star's failure to notify the Cavallos during the period before it notified the EPA, thus are not preempted by the EPA Orders.

The EPA Orders did encompass all of Star's remediation efforts, so failures "to properly and promptly remediate and recover/remove the Petroleum Releases" are likely to be preempted. Similarly, the Cavallos allege that venting was "regularly performed," apparently under EPA supervision, so claims of improper venting probably are preempted. Even remediation and venting, however, are actionable if Star tortiously failed to notify the EPA of the releases—a jury might find, for instance, that the delay

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[8] The district court held that claims based on events before December 8, 1991, are barred by the statute of limitations, *see supra* part III.B, and the Cavallos do not appeal that ruling, *see supra* n.2.

after the December 1991 spill was negligent—or if Star improperly implemented EPA instructions.

In sum, the fact that allegedly tortious conduct occurred within the temporal and subject-matter scope of an EPA Order does not necessarily compel preemption of a damages claim based on that conduct. We cannot conclusively determine, from the face of the Complaint and the text of the EPA Orders, that the Orders or EPA instructions pursuant to the Orders compelled all of Star's allegedly improper activities and its manner of performing them. Thus we cannot determine whether damages based on those activities would conflict with EPA authority, or, in turn, whether the preemption doctrine applies.

C

The Cavallos assert that, because their claims are grounded in Virginia state law and originally were filed in Virginia state court, the admissibility of expert testimony should be governed by Virginia law. As Star points out, however, this court held expressly in *Scott v. Sears, Roebuck & Co.* that federal rules apply to the admission of expert testimony in diversity cases:

> Unlike evidentiary rules concerning burdens of proof or presumptions, the admissibility of expert testimony in federal court sitting in the diversity jurisdiction is controlled by federal law. State law, whatever it may be, is irrelevant.

789 F.2d 1052, 1054 (4th Cir. 1986). But the Cavallos respond that *Daubert*, which was decided seven years after *Scott*, implemented a heightened burden of proof—"established toxicological methodology" instead of "greater weight of all the evidence." Because *Scott* specifically excepted burdens of proof, they contend, the rule it established is invalid after *Daubert* and Virginia law should apply. Their argument is meritless. A standard for admission of testimony, however stringent, is not a burden of proof. *Daubert* governs whether evidence is admitted,

not how persuasive it must be to the factfinder. Consequently, *Scott* remains good law even after *Daubert*, and the district court correctly applied federal law in determining whether to admit the experts' testimony.

On the merits of the expert-testimony question, the Cavallos' brief succinctly stated the essence of their position:

> The trial court concluded that neither Dr. Bellanti nor Dr. Monroe strictly adhered to the established toxicological methodology in forming their conclusions that Ms. Cavallo's exposure to AVJet vapors from the December 1991 spill caused her various chronic illness[es], and that their testimony, therefore[,] is not supported by appropriate validation as required by *Daubert v. Merrell Dow*, 113 St.Ct. at 2795.

Cavallos' Brief at 17 (citation to Joint Appendix omitted).

The parties agree that *Daubert* is the leading case on this issue. But neither party emphasizes that the Supreme Court itself viewed *Daubert* as a liberalization, not a tightening, of the rules controlling admission of expert testimony. The Court recognized that the question had been governed for seventy years by the standard first set out by the D.C. Circuit in *Frye v. United States*—that scientific expert testimony must be based on principles that are "sufficiently established to have gained *general acceptance* in the particular field in which [they] belong[]," 293 F. 1013, 1014 (D.C. Cir. 1923) (emphasis added). It held, however, that the *Frye* test had been superseded by Fed. R. Evid. 702.

Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise.

The *Daubert* Court noted that Rule 702 does not mention *Frye*'s "general acceptance" test. Moreover, it stated:

> A rigid "general acceptance" requirement would be at odds with the "liberal thrust" of the Federal Rules and their "general approach of *relaxing* the traditional barriers to 'opinion' testimony." *Beech Aircraft Corp. v. Rainey*, 488 U.S. [153,] 169 (1988). . . . That austere standard, absent from and incompatible with the Federal Rules of Evidence, should not be applied in federal trials.

113 S. Ct. at 2794 (emphasis added) (citations to non-quoted sources omitted).

The *Daubert* Court held that two questions control admission of scientific expert testimony: "whether the reasoning or methodology underlying the testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 2796. In lieu of the *Frye* test, it decided, the validity of the methodoolgy or reasoning is determined using a flexible inquiry based on five factors: (1) whether the testimony has been tested, (2) whether it has been published or exposed to peer review, (3) its rate of error, (4) whether there are standards and controls over its implementation, and (5) whether it is generally accepted. *Id.* at 2796-97. If valid, the Court wrote, whether the testimony can "properly be applied to the facts in issue" is determined by reference to other rules of evidence, *id.* at 2797, such as the relevance and prejudice provisions of Rule 401, *id.* at 2794, and Rule 403, *id.* at 2798.

The *Daubert* Court concluded by reemphasizing that scientific evidence is to be admitted more liberally under Rule 702 than it was under *Frye*, and that exclusion is the least favored means of rendering questionable scientific evidence ineffective:

> Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence. Additionally, in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment, and likewise to grant summary judgment. These conventional devices, rather than wholesale exclusion under an uncompromising "general acceptance" test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702.

Id. at 2798 (citations omitted).

In the instant case, the district court concluded that the bases of the doctors' opinions were not sufficiently established to warrant their admission into evidence:

> In sum, neither Dr. Monroe nor Dr. Bellanti sufficiently adhered to the established toxicology methodology in forming [his] conclusions that Ms. Cavallo's exposure to AVJet vapors from the December 1991 spill caused her various chronic illnesses. Their testimony, therefore[,] is not "supported by appropriate validation" as required by *Daubert*, and is ultimately unreliable. In the final analysis, the opinions of Drs. Monroe and Bellanti are based largely on hypothesis and speculation. This is not to say that the doctors are insincere in their opinions, or that their opinions may not some day be validated through scientific research and experiment. It may well be that the AJet spill forever "sensitized" Ms. Cavallo to petroleum vapors and various other household chemicals. But the published scientific literature and test results simply do not support that conclusion at this time. And the

price paid for this seemingly stringent standard of reliability is that, unavoidably, some legitimate injuries will be left unredressed.

Memorandum Opinion at 39-40, *in* Joint Appendix at 1799-800 (footnotes omitted).

The district court's interpretation is restrictive in this case, but it is not inconsistent with *Daubert*. Although *Daubert* eliminated the requirement of general acceptance, the five factors it established still require that the methodology and reasoning used by a witness have a significant place in the discourse of experts in the field. The district court determined that the testimony of Dr. Bellanti and Dr. Monroe did not have such a place. By making that determination, the court properly exercised its discretion. The Cavallos have shown that the question of admission is close, but we defer to the court's decision to exclude the evidence and affirm its summary judgment on Count I.

IV

The face of the Complaint and the text of the EPA Orders are insufficient to determine whether EPA involvement preempts Count II, the loss and use and enjoyment claim of Count III, and Count IV. Whatever the preemption doctrine's effect, however, the personal injury claim of Count III does not state a claim under Virginia law. Moreover, the district court acted within its discretion by excluding testimony by the Cavallos' experts. Accordingly, we affirm the district court's summary judgment on Count I and its dismissal of the personal injury claim of Count III, but we reverse its dismissal of Count II, the loss of use and enjoyment claim of Count III, and Count IV and remand them for further proceedings.

AFFIRMED IN PART AND REVERSED AND REMANDED IN PART

[Not for Publication]

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 96-1287

ELIZABETH V. BOGOSIAN,
Plaintiff, Appellant,
v.

MERCEDES-BENZ OF NORTH AMERICA, INC.
and DAIMLER-BENZ NORTH AMERICA CORPORATION,
Defendants, Appellees.

Appeal from the United States District Court
for the District of Rhode Island
[Hon. Francis J. Boyle, *Senior U.S. District Judge*]

Before Torruella, *Chief Judge*,
Bownes, *Senior Circuit Judge*,
and Stahl, *Circuit Judge*

November 21, 1996

STAHL, *Circuit Judge*. After being struck and injured by a rolling automobile, plaintiff-appellant Elizabeth V. Bogosian commenced this diversity action in Rhode Island District Court alleging strict product liability, negligence and breach of warranty against Mercedes-Benz of

North America, Inc. ("Mercedes-Benz") and Daimler-Benz North America Corporation.[1] The jury returned a verdict in favor of Mercedes-Benz on the strict liability claim, the only liability theory it considered.[2] Bogosian appeals, contending that the district court committed reversible error in (1) granting judgment as a matter of law in favor of Mercedes-Benz on the negligence claim, (2) excluding one of her expert witnesses, (3) excluding evidence of a product modification occurring after the manufacture of the automobile in question, but before the injurious event, and (4) denying her motion for new trial.

I.

Facts and Prior Proceedings

The facts are largely undisputed. On July 9, 1992, Bogosian drove her daughter's 1986 Mercedes Benz 560 SEL automobile ("560 SEL") to her home and pulled into the parking area adjacent to the driveway. The pavement on which she parked sloped slightly toward the rear of the car. According to her testimony, Bogosian placed the transmission gear selector lever, located on the console shift between the front driver and passenger seats, in the park position. She did not set the parking brake. She then removed the ignition key, locked the car doors, and walked toward her house. Upon approaching her front

[1] There is no indication in the record that Daimler-Benz of North America Corporation had any pertinent involvement (by way of design, manufacture, distributorship, sales, or otherwise) with the vehicle that injured Bogosian. At oral argument before this court, counsel for Bogosian was unable to clarify the status of this party-defendant, while counsel for Mercedes-Benz explained that the entity was a holding company, and confirmed that it had no relevant connection to the action. In the absence of any contrary assertion, we treat this case as involving only Mercedes-Benz of North America, Inc., the distributor of the vehicle.

[2] The breach of warranty claim, apparently disposed of at the summary judgment stage, is not at issue in this appeal.

door, she decided to check her mail and retraced her steps to the mailbox located near the street. As she was retrieving the mail, the 560 SEL—which had rolled from the parking area—struck her, knocked her down, and ran over her ankle, causing serious injury.

In July 1994, Bogosian sued the distributor[3] of the automobile (but not the manufacturer) to recover damages for her injuries. Underlying her tort claims were two design defect theories: (1) the absence of a "park ignition interlock," which would have prevented her from removing the ignition key if the vehicle was not in park gear, and (2) the existence of a "false park detent": a tactile phenomenon whereby the operator senses that the park gear is selected but in fact, the gear selector lever is not fully engaged in park.

II.

Judgment As a Matter of Law

Bogosian challenges the district court's grant of Mercedes-Benz's motion, pursuant to Fed. R. Civ. P. 50(a), for judgment as a matter of law on her negligence claim. The court granted the motion at the close of Bogosian's case in chief upon finding that she failed to produce evidence to establish an automobile distributor's standard of care. We review the grant of a Rule 50(a) motion *de novo*, considering the evidence and reasonable inferences therefrom in the light most favorable to the non-movant. *Andrade* v. *Jamestown Hous. Auth.*, 82 F.3d 1179, 1186 (1st Cir. 1996). The court may grant the motion only if the evidence, so viewed, would not permit a reasonable jury to find for the plaintiff on her claim. *Id.*

[3] The parties describe Mercedes-Benz as both the "distributor" and "seller" of the 560 SEL in question. For simplicity, we refer to Mercedes-Benz as the "distributor" only.

Under Rhode Island law, "[i]n order to sustain a cause of action for negligence the plaintiff is required to establish a standard of care as well as a deviation from that standard." *Marshall* v. *Tomaselli*, 372 A.2d 1280, 1283 (R.I. 1977). Thus, we review the record to determine if Bogosian introduced evidence sufficient to permit a reasonable jury to conclude that Mercedes-Benz deviated from some pertinent standard of care.

At trial, there was evidence that (1) the automobile industry first began to use park ignition interlocks [4] more than ten years before the 1986 sale of the 560 SEL, (2) by 1986, all vehicles sold in the United States having a gear shift *on the steering column* were equipped with the park interlock device, and (3) by 1986, 40% of vehicles that had a gear shift on the console (as did the 560 SEL) were equipped with the device. There was also testimony that installation of the park ignition interlock would result in a cost to the consumer of five to seven dollars. Bogosian contends, as she did below, that from this evidence the jury could have found that, in 1986, a distributor of a 560 SEL knew or should have known that the safety of the vehicle depended upon a park ignition interlock, and thus, a reasonably prudent distributor would have installed the inexpensive park ignition interlock mechanism.[5]

[4] The park ignition interlock acts to prevent a driver from removing the ignition key if the gear selector is in any position other than park.

[5] Our review of the transcript of the arguments on the Rule 50(a) motion reveals that Bogosian did *not* advance a "failure to warn" theory of negligence. We note first that there was no evidence introduced tending to establish what would have been an adequate warning, on the part of a distributor, with regard to the absence of a park ignition interlock. Moreover, having failed to raise before the district court any issue with regard to this possible theory, Bogosian has failed to preserve it for appeal. *See Wainwright Bank & Trust Co.* v. *Boulos*, 89 F.3d 17, 23 n.2 (1st Cir. 1996). Finally, other than quote the text of the Restatement of

Bogosian was required to produce evidence that the distributor of the 560 SEL deviated from a standard of care when it failed to install the park ignition interlock mechanism on her automobile. *See Scittarelli* v. *Providence Gas Co.*, 415 A.2d 1040, 1043 (R.I. 1980) (requiring plaintiff, under negligent inspection and test claim against a distributor, to "establish a standard of care with respect to inspection and testing and the defendant's deviation from that standard"). She presented no evidence—either through customary distributor practices, past practices, or expert testimony—to establish a standard of care by which Mercedes-Benz, as distributor, should have operated. Having utterly failed to establish that Mercedes-Benz acted below a minimum standard of care when it failed to install the park ignition interlock, Bogosian could not have prevailed on her negligence claim. Thus, the district court did not err in granting judgment as a matter of law in favor of Mercedes-Benz on this claim.[6]

III.

Expert Testimony on "False Park Detent" Theory

Bogosian contends that the district court erroneously excluded the proposed expert testimony of Joseph Davidson on the false park detent theory. After conducting an extensive voir dire, the court ruled that Davidson's testimony was inadmissible for three reasons: (1) it was not within Davidson's expertise to opine on the issue of trans-

Torts (Ssecond) § 401, Bogosian on appeal does nothing to hint at any developed argumentation on a failure to warn theory. *Ryan* v. *Royal Ins. Co. of Am.*, 916 F.2d 731, 734 (1st Cir. 1990) (explaining that appellate arguments adverted to perfunctorily are deemed abandoned). Thus, we will not consider Bogosian's arguments with respect to her negligence claim under a failure to warn theory.

[6] *See Tokio Marine & Fire Ins., Co.* v. *Grove Mfg. Co.*, 958 F.2d 1169, 1172 (1st Cir. 1992) (upholding directed verdict on negligence claim where plaintiff failed to present evidence of standard of care).

mission design; (2) his methodology in examining the 560 SEL to determine the cause of Bogosian's injury was unreliable; and (3) the factual foundation for his testimony was inadequate because Bogosian was unable to establish that the vehicle was in substantially the same condition at the time Davidson tested it as it was when the accident occurred.

A. Rule 702 Requirements and Standard of Review

When faced with a proffer of expert testimony, the district court must determine whether the expert witness is qualified and has specialized knowledge that will "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702; *see generally United States* v. *Sepulveda*, 15 F.3d 1161, 1183 (1st Cir. 1993) (citing *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 591 (1993)), *cert. denied*, 114 S. Ct. 2714 (1994). First, the court has broad discretionary powers in determining whether or not the proposed expert is qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702; *see generally Richmond Steel, Inc.* v. *Puerto Rican Am. Ins. Co.*, 954 F.2d 19, 21 (1st Cir. 1992). Next, the court decides if the proposed subject matter of the expert opinion properly concerns "scientific, technical, or other specialized knowledge." Fed. R. Evid. 702. Finally, the court performs a gatekeeping function to ascertain whether the testimony is helpful to the trier of fact, *i.e.*, whether it rests on a reliable foundation and is relevant to the facts of the case. *See Vadala* v. *Teledyne Indus., Inc.*, 44 F.3d 36, 39 (1st Cir. 1995); *see also Daubert*, 509 U.S. at 591 (characterizing this consideration as one of "fit.").

"Because gauging an expert witness's usefulness is almost always a case-specific inquiry, the law affords trial judges substantial discretion in connection with the admission or exclusion of opinion evidence." *Sepulveda*, 15 F.3d at 1183. Thus, we will uphold the district court's

ruling in this area unless it is "manifestly erroneous." *Salem* v. *United States Lines Co.*, 370 U.S. 31, 35 (1962). With the foregoing precepts in mind, we turn to the facts of this case.

B. Qualifications

The record establishes that Davidson earned a Bachelor of Science degree in industrial and vocational education, and had been certified to teach vocational automobile mechanics. At the time of trial, he was certified by the National Institute for Automotive Service Excellence as a master automobile technician for diagnosis and repair of various vehicles, including passenger cars. He worked as an automobile mechanic from 1952 to 1967. Shortly thereafter, he became a "consultant in forensic automotive mechanics," now his full time employment.[7]

Davidson does not have an engineering degree, and his formal education in engineering was apparently limited to three semesters of "basic" electrical engineering courses at Carnegie-Mellon University before he dropped out. He explained that his hands-on experience made him familiar with automatic transmissions. He conceded that he had never professionally designed a component for an automobile, although he had done so "in the courtroom." He also conceded that he had never designed a transmission or a gear shift selector, and had no formal training in manufacturing automobiles or their components. He saw neither design drawings nor specifications of the 560 SEL, although he had reviewed service literature and "cutaway" drawings for the automobile. Of the 126

[7] When asked the meaning of the word "forensic" in this capacity, Davidson replied: "There are a number of meanings to the word 'forensic.' . . . It has to do with applying scientific principles to a problem using scientific techniques and technology. Another is 'suitable for use in the courts.' Still another is to persuade by convincing arguments. So all those meanings come together in the kind of work I do."

prior times that he had testified as an expert, only one of them involved the false park detent phenomenon.

Because Davidson would have testified that the false park detent rendered the 560 SEL dangerous, and he would have offered a corrective modification, the district court found that he essentially would have opined on the central issue of design defect.[8] The court acknowledged that Davidson was "a very well qualified master mechanic," but ruled that his expertise did not extend to the design defect issue at hand. On appeal, Bogosian challenges this ruling, which we review for clear error. *See Richmond Steel, Inc.*, 954 F.2d at 21; *DaSilva* v. *American Brands, Inc.*, 845 F.2d 356, 361 (1st Cir. 1988).

The record establishes that, at most, Davidson had extensive experience in automotive repair. His background shows a lack of any significant expertise—by way of knowledge, skill, experience, training, or education—in relevant areas such as the design or manufacture of automobiles or their components. *See Tokio Marine & Fire Ins. Co.* v. *Grove Mfg. Co.*, 958 F.2d 1169, 1175 (1st Cir. 1992) (upholding exclusion of proposed expert in design defect case where, *inter alia*, witness lacked familiarity in product's design, manufacture, marketing and applicable industry standards). While not dispositive, the lack of a mechanical engineering degree or other engineering expertise certainly calls into question Davidson's ability to criticize the design of a transmission parking mechanism and its operation under various circumstances.[9]

[8] Although Bogosian insisted that Davidson would not testify about design, but would only explain how the transmission worked, the record supports the court's finding that Davidson's conclusions embraced the subject of transmission design and defect; in the absence of clear error, we will not disturb this finding.

[9] *See, e.g., DaSilva*, 845 F.2d at 361 (finding mechanical engineer with twenty-three years of engineering experience and "extensive experience evaluating and recommending safety devices for machines" qualified to testify regarding safety design of industrial mixer);

On this background, we find no clear error in the district court's finding that Davidson was not qualified to opine on the issue of a transmission design defect.

C. Underlying Methodology

Davidson would have testified that he first identified the false park detent phenomenon in January 1979. He would have explained that a false park detent can occur when the gear selector lever is not placed completely in the park notch, which is set off to the left in the console shift, a position referred to as "latched park." *See* Appendix A. When the selector level is in latched park, the vehicle will not roll any appreciable distance. A position just short of latched park, however, could produce a false park detent—a tactile sensation that the car is fully in park gear. In this situation, the car is susceptible to rolling.[10]

Davidson would have testified that this false park detent is felt when one shifts rapidly from drive towards park, but fails to fully engage in the latched park position. He stated that if one were to look closely at the console shift, one would be able to see if the selector level was in a position, *e.g.*, between reverse and park, that would indicate the possibility of a false park detent. He explained that if the operator shifted slowly and carefully into park, he or she could not leave the selector level in anything

Kallio v. *Ford Motor Co.*, 391 N.W.2d 860, 861 (Ct. App. Minn. 1986) (describing testimony of various mechanical engineering experts in case where alleged transmission design defect created a "false park"), *aff'd*, 407 N.W.2d 92 (Minn. 1987).

[10] Davidson would have explained that, in a false park detent situation, the vehicle could roll because the park pawl in the transmission park mechanism was only "tip engaged" and the spring in the park linkage was not fully compressed. When the vehicle was in latched park, on the other hand, the park pawl would lock into the park slot on the park gear, thereby preventing the car from rolling.

but latched park.[11] He also stated that if the operator sees that the gear selector level is in the latched park position (*i.e.*, set off to the left), the false park detent phenomenon has no application.

With respect to his investigation of the facts of this case, Davidson stated that, in January 1994, he questioned Bogosian about the July 1992 events leading up to her injury. He examined the parking area of her home and measured the grade of the approximate location on which she had parked just before the 560 SEL rolled. He then travelled to an automobile garage, Fred's Autohaus, where the automobile was located. At the garage, Davidson tested and experimented with the action of the park lock in the vehicle's transmission mechanism.[12]

Based on his testing of the 560 SEL's transmission park mechanism, Davidson would have testified that the vehicle was capable of a false park detent. He would have opined that this phenomenon rendered the vehicle defective and unreasonably dangerous, and he would have offered a corrective solution involving a part modification. While the record is unclear on this point,[13]

[11] Because the gear selector lever is spring-loaded to the left, once the lever is sufficiently pushed forward towards the park position, it pulls to the left into the latched park position.

[12] Specifically, he first tested the transmission gear shifter to confirm that it was in good adjustment, then placed the selector lever in park. He lifted the right rear wheel off the ground, and turned it until the park pawl in the transmission locked into the park slot, *i.e.*, until the car was fully locked into park gear and the wheel would no longer turn. At that point, he moved the gear selector lever out of park and turned the right rear wheel further so that when he shifted back into park, the park pawl would hit the tip of the tooth on the park gear rather than drop straight in to the park slot. Thus, in order for the car to shift fully into latched park, the spring in the park pawl linkage inside the transmission would have to be compressed.

[13] The record before us does not contain a copy of Davidson's curriculum vitae, his report, supporting documents or exhibits, or

Davidson presumably would have opined that, given Bogosian's insistence that she placed the gear selector lever in park before exiting the automobile, this defect, in combination with the slight slope of the parking area, led to her injury.

Citing *Daubert*, the district court expressed its concern with the reasoning and methodology underlying Davidson's opinion. The court stated:

> Here the proffered evidence is that the vehicle was in a garage, the rear wheel was lifted and rotated, and the shift lever placed in a particular position with a result from which the witness apparently would extrapolate the conclusion that this is the way Plaintiff was injured. But there is no evidence that the so-called test that was used was anything that even remotely resembled a known technique. No proffer of any kind of scientific journal or paper, nothing of that sort to show that this is the way you find out that sort of thing.

The court further remarked that the "appropriate design of part of an automobile having to do with keeping it at rest after the car is stopped and the driver has left the driver's seat" was a "scientific" issue.

Bogosian contends that the court committed reversible error because it wrongly characterized the subject of Davidson's testimony as "scientific" rather than "technical," and thus, *Daubert* was inapplicable. Assuming *arguendo* that this case does not involve "scientific law" (and thus, *Daubert*'s holding does not apply), we must then consider "*Daubert*'s countervailing precept: that the trial judge is assigned 'the task of ensuring that an ex-

any other aspects of his proffer other than the transcript of the court proceedings. To the extent that the absence of any of these items creates any material doubt, that doubt is resolved against the appellant, Bogosian. *See LaRou* v. *Ridlon*, —— F.3d ——, No. 96-1229, 1996 WL 606436, at *5 (1st Cir. Oct. 28, 1996).

pert's testimony both rests on a reliable foundation and is relevant to the task at hand.' " *Vadala*, 44 F.3d at 39 (quoting *Daubert*, 509 U.S. at 597). Thus, even if *Daubert*'s specific discussion of the admissibility of scientific principles did not strictly apply to Davidson's testimony, the admissibility of the testimony was still controlled by the requirement of factual relevance and foundational reliability. *See* 509 U.S. at 591-92.

Here, the district court was troubled by Davidson's procedures in investigating the applicability of his false park detent theory to this case. Davidson examined the vehicle away from the site of the accident. He did not, in any way, attempt to replicate the known facts surrounding the injury-producing event, but rather, tested his theory by raising a rear wheel of the vehicle as it sat in Fred's Autohaus. On the record before us, it appears that Davidson did little more than come to the unremarkable conclusion that the vehicle's wheels would not turn when the gear selector lever was in latched park, but that they would turn when the lever was in any other position. *See supra* notes 12 & 13.

Moreover, Davidson's conclusion that a false park detent caused the injury-producing events assumed that Bogosian shifted the selector lever rapidly from drive towards park, and that she left the lever in a position short of latched park. First, there was no evidence as to the speed with which Bogosian shifted the selector lever. More importantly, Bogosian repeatedly testified that she looked at the console shift before exiting the vehicle and saw the selector lever in latched park. She steadfastly maintained this position, even after prompting from a generously worded question by her counsel on redirect examination. While, of course, the jury could have disregarded plaintiff's own testimony, it does little to tie the facts of this case to Davidson's proffered opinion, especially given his concession that there could be no false park detent if the vehicle operator observed the selector

lever in latched park. The district court appropriately found it very odd that Bogosian would present an expert witness who would testify that her own unwavering testimony was incorrect.

In the end, the district court clearly was not persuaded that Davidson's opinion rested upon a reliable factual and methodological foundation. While the district court may have inartfully cited *Daubert* in making its ruling, we cannot say that it abused its substantial discretion when finding inadequate the premises of the proposed testimony.

D. Substantially Same Condition

The district court's final concern with the proposed expert testimony was the lack of evidence to validate the condition of the 560 SEL at the time of Davidson's examination. Davidson tested the transmission parking mechanism on the automobile in January 1994, approximately one and a half years after the accident. Before Davidson's inspection, a "series of engineers" examined the vehicle on behalf of both Bogosian and Mercedes-Benz. At some point, the vehicle was transported to Fred's Autohaus, where it was placed on a lift; at yet some other unspecified time, the vehicle was sold to a third party. The court indicated that, given these events, Bogosian would have to present evidence sufficient to establish that the transmission mechanism was in substantially the same condition at the time of Davidson's tests as it was at the time of the accident.

In response to the court's concerns, Bogosian offered the testimony of her daughter, Evan Perri (the owner of the 560 SEL), who would have testified as to the physical whereabouts of the automobile during the time in question. Perri had no knowledge, however, about the tests or examinations performed during the various inspections. The court concluded that without the testimony of those who inspected the transmission before Davidson, Bogosian could not establish that Davidson's conclusions rested upon a reliable factual foundation.

Where, as here, a conclusion that a product was defective derives from a test or examination of it, there must be sufficient evidence to support a finding that the product was in substantially the same condition—in relevant respects—when tested as it was at the time of the accident. The absence of such a showing renders irrelevant any testimony based on the test or examination. *See Kukuruza* v. *General Elec. Co.*, 510 F.2d 1208, 1211-12 (1st Cir. 1975) (requiring a prima facie showing of substantial identity of the product's condition at the time of the accident and the time of inspection); *cf. Fusco* v. *General Motors Corp.*, 11 F.3d 259, 263-64 (1st Cir. 1993) (requiring a foundational showing of substantial similarity in circumstances between proffered demonstration and actual events).

Given that a number of experts examined and tested the 560 SEL in an attempt to determine why it unexpectedly rolled, the district court was warranted in requiring Bogosian to come forward with evidence sufficient to prove that those experts did not disturb the transmission mechanism in any material respect. *See Williams* v. *Briggs Co.*, 62 F.3d 703, 707-08 (5th Cir. 1995) (upholding exclusion of testimony about water heater malfunction where the expert conducted a test two years after the accident and after various, unspecified repairs were made); *see also Romano* v. *Ann & Hope Factory Outlet, Inc.*, 417 A.2d 1375, 1379-80 (R.I. 1980) (upholding, under Rhode Island evidence laws, trial court's discretionary exclusion of design-defect testimony where the expert examined the bicycle two years after the accident and after a previous expert's experiments) (collecting cases).

Because neither Davidson nor Perri was competent to establish the requisite similarity of condition, there was no evidentiary link between the condition of the transmission in July 1992 and in January 1994.[14] On these

[14] Although Davidson viewed service literature and "cutaway" drawings for the 560 SEL, he made no representations as to the relevance or accuracy of these documents with respect to the vehicle's transmission at either the time of the accident, or his examination, or both. More importantly, Davidson's January 1994 tests, not these documents, formed the basis of his testimony.

facts, Bogosian failed to make a prima facie showing that the condition of the transmission at the time of Davidson's testing was substantially similar to that on the accident date. Thus, we conclude that the court properly excluded Davidson's expert opinion, in part, on this basis. *See* Fed. R. Evid. 104(b) & advisory committee's note concerning (conditionally relevant evidence); *United States* v. *Wilson*, 798 F.2d 509, 515-16 (1st Cir. 1986) (explaining that a district court enjoys broad discretion in determining the admissibility of conditionally relevant material).[15]

In conclusion, we have considered carefully Bogosian's arguments and the record before us, and, for all of the foregoing reasons, we do not find the district court's decision to exclude Davidson's testimony to be manifestly erroneous.

IV.

Subsequent Remedial Measures

Bogosian claims error in the district court's refusal to allow her to question Mercedes-Benz's expert witness regarding the installation of park ignition interlocks on Mercedes-Benz vehicles apparently beginning with the 1990 model year. The installation of this interlock device occurred after the 1986 sale of the 560 SEL at issue here, but before Bogosian's accident in 1992. Bogosian argues that evidence of the modification was admissible because (1) Mercedes-Benz contested its feasibility, and, (2) in any event, Federal Rule of Evidence 407, which prohibits evidence of subsequent remedial measures under

[15] *See also Vadala*, 44 F.3d at 39 (finding witness's expertise irrelevant where the opinion lacked substantial factual basis); *United States* v. *Sorrentino*, 726 F.2d 876, 885 (1st Cir. 1984) (same).

certain circumstances, is inapplicable on the facts of this case.

Before trial, Mercedes-Benz stipulated to the feasibility of installing the park ignition interlock in 1986, and moved in limine for the exclusion of evidence regarding its use beginning 1990. During trial, Bogosian was allowed to introduce evidence regarding the feasibility of a park ignition interlock mechanism on a vehicle such as the 1986 560 SEL, to wit: its low cost and simple installation procedure. This evidence was uncontroverted. Subsequently, on cross-examination of Mercedes-Benz's only witness, Axel Stehle—the manager of product analysis at Mercedes-Benz—Bogosian asked if it was feasible in 1986 for Mercedes-Benz to equip the 560 SEL with the mechanism. Stehle, who had not testified about the subject on direct examination, answered, "Not to my knowledge." [16] At this, Bogosian sought to question Stehle about the subsequent modification. The court refused to allow the questioning, characterizing it as "bootstrapping."

Although this circuit has recognized that Federal Rule of Evidence 407 applies to strict liability cases, *see Raymond* v. *Raymond Corp.*, 938 F.2d 1518, 1523 (1st Cir. 1991), it does not apply where, as here, the modification took place before the accident that precipitated the suit. *Id.* In cases such as this, the district court may, if necessary, exclude evidence of the remedial modification by resort to its considerable discretion under Rule 403, which permits the exclusion of relevant evidence if its probative value is substantially outweighed by the danger of unfair prejudice or misleading the jury. *See* Fed. R. Evid. 403; *Raymond*, 938 F.2d at 1523-24.

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[16] Although Stehle explained on direct that Mercedes-Benz chose to utilize a *steering* ignition interlock—which prevented normal steerability when the key was removed from the ignition—in order to comply with a federal standard, Stehle never opined on the issue of whether or not Mercedes-Benz was capable of installing the park ignition interlock in 1986.

A strict liability claim centers on the condition of the product " 'at the time it leaves the seller's hands.' " *Ritter* v. *Narragansett Elec. Co.*, 283 A.2d 255, 262 (R.I. 1971) (quoting Restatement (Second) of Torts § 402A cmt. g). For this reason,

> the introduction of evidence of pre-accident design modifications not made effective until after the manufacture of the allegedly defective product may reasonably be found unfairly prejudicial to the defendant and misleading to the jury for determining the question whether the product was unreasonably dangerous at the time of manufacture and sale.

Raymond, 938 F.2d at 1524. Thus, the district court may supportably exclude evidence of post-manufacture, pre-accident design modifications if its probative value is substantially outweighed by its prejudicial effects. *Id.*

Here, Mercedes-Benz stipulated pretrial that the park ignition interlock was a feasible modification in 1986. Accordingly, it did not controvert Bogosian's evidence regarding the ease with which Mercedes-Benz could have installed the mechanism, nor did it present testimony that the mechanism would have been impractical or impossible. Thus, the jury had before it uncontroverted evidence that Mercedes-Benz could have implemented the modification during the relevant time frame; any evidence that Mercedes-Benz, in fact, later modified its vehicles risked the danger that "jurors would too readily equate subsequent design modifications with admissions of a prior defective design." *Id.* at 1523. Given this, the court appropriately prohibited Bogosian from exploring the topic on cross-examination of Stehle, and further recognized that Bogosian was attempting to create a feasibility dispute where there was none.[17] Finally, having failed to

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[17] *See Albrecht* v. *Baltimore & Ohio R.R. Co.*, 808 F.2d 329, 331 (4th Cir. 1987) ("It is not for the plaintiff to put feasibility in issue, for feasibility is not in issue unless and until controverted

offer the stipulation to be read to the jury, Bogosian cannot now complain that such a reading would have been ineffective. We find that the district court did not abuse its considerable discretion in its treatment of this matter.

V.

Motion for New Trial

Bogosian argues that the district court erred in denying her motion for new trial. *See* Fed. R. Civ. P. 59. Bogosian contends that the evidence established that Mercedes-Benz knew or should have known that vehicle safety depended on the installation of a park ignition interlock, and that the lack of the interlock rendered the 560 SEL unreasonably dangerous and caused Bogosian's injury. Bogosian further asserts that, because the 560 SEL rolled, the gear selector lever must have only *appeared* to have been in the latched park position. Thus, she argues, "[t]he obvious inference to be drawn is that, in the absence of the car having been pushed by little green men, the car rolled because it was *not fully engaged* in the [latched park] position."

We review for abuse of discretion the denial of a Rule 59 motion for new trial. *Fernandez* v. *Corporacion Insular de Seguros*, 79 F.3d 207 (1st Cir. 1996). A new trial is warranted "only if the verdict, though rationally based on the evidence, 'was so clearly against the weight of the evidence as to amount to a manifest miscarriage of justice.'" *Id.* (quoting *Lama* v. *Borras*, 16 F.3d 473, 477 (1st Cir. 1994)).

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by the defendant."); *Gauthier* v. *AMF, Inc.*, 788 F.2d 634 (9th Cir. 1986) (explaining that, where defendant neither introduces evidence of infeasibility nor argues it, plaintiff may then "introduce evidence of feasibility other than subsequent remedial measures and could argue that defendant had not disputed the point." (quotation and citation omitted)), *amended by*, 805 F.2d 337 (9th Cir. 1986).

The district court instructed the jury that, to prevail on her strict product liability claim, Bogosian had to establish that the 560 SEL was in a defective condition unreasonably dangerous to the consumer, and that the defect caused her injury. *See Ritter*, 283 A.2d at 261 (citing Restatement (Second) of Torts § 402A for elements of strict product liability claim). There was evidence that the gear selector lever of the 560 SEL was in good working condition, and, when placed in full latched park, the vehicle would not roll. Thus, despite Bogosian's adamant testimony to the contrary, the jury could infer from the fact that the vehicle rolled that it was not in latched park just prior to her injury. The jury could also infer that a park ignition interlock would have prevented Bogosian from removing the ignition key, as she did, before she exited the vehicle.

For Bogosian to prevail on her claim, however, the jury had to find that the absence of a park ignition interlock constituted an *unreasonably dangerous* defect. A defect renders a product "unreasonably dangerous" if it "establishes a strong likelihood of injury to the . . . consumer . . . who is unaware of the danger involved in the use of a product in a way it was intended to be used or in using the product in a normal manner." *Ritter*, 283 A.2d at 263. Accordingly, the district court instructed the jury that a seller of a product does not have a "duty to provide an accident proof, perfect or foolproof product." The evidence established that only 40% of motor vehicles sold in the United States in 1986 with a console shift were equipped with a park interlock system. Moreover, there was conflicting evidence regarding whether, in 1986, the interlock mechanism was a safety or an anti-theft device. There was also evidence that the parking brake was in good order, and that, if Bogosian had used it as directed in the owner's manual, the vehicle would not have rolled regardless of the position of the gear selector lever. On this evidence, the jury was not compelled to find for Bogosian on her strict product liability

theory. We find that the district court did not abuse its discretion in denying the new trial motion.

VI.

Conclusion

For the foregoing reasons, we *affirm* the judgment of the district court in all respects. *Costs to appellees.*

[Appendix omitted.]

(23)

No. 96-188

In The Supreme Court of the United States

October Term, 1996

General Electric Company, *et al.*,
Petitioners,

v.

Robert K. Joiner, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

JOINT APPENDIX

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525 pp

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NOTICE

The following items have been omitted in printing this appendix because they appear on the following pages in the printed appendix to the petition for certiorari, and are incorporated herein by reference:

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Certificates of service wherever appended to documents appearing herein have been omitted in printing.

STATE COURT OF FULTON COUNTY
STATE OF GEORGIA

DOCKET ENTRIES

——CASE——

CASE NO: 92VS0061273 ANNEX: DOWNTOWN
JURISDICTION: ST. CIVIL
CASE TYPE: TORT CASE FILED: 08/05/92
RESTRICTED FILE: AMT $300: YES
JURY DEMAND: YES RUSH PAPERS:

NO. SUMMONS: 03 MRSHL SV GHSE:

JUDGE: JERRY W BAXTER
****SUMMARY DATA** STATUS: ACTIVE**
PLTF: JOINER, ROBERT K
DEFN: GENERAL ELECTRIC COMPANY
DATE JUDGE ASSGN: 08/06/92
TIME JUDGE ASSGN: 1528
NO CLAIMS: 01 NO OPEN CLAIMS: 01
LAST ACTION: ANSWER
DATE: 09/04/92 CONT: NOT CONT.
DISPOSITION:
COLL CLOSE DT: 08/06/92 NO COLL RECS: 01

• • • •

——DEFENDANT——

CASE NO: 92VS0061273 L/D SEQ: 01 NAME:
GENERAL ELECTRIC COMPANY
NAME DESC: A NEW YORK CORPORATION
SHORT NAME: GENERAL EL
ADDRESS: c/o C T CORP SYSTEM
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CITY: ATLANTA STATE: GA ZIP: 30361
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SHORT NAME: MONSANTO C
ADDRESS: c/o PRENTICE HALL CORP SYSTEM
ADDRESS: 66 LUCKIE ST CITY: ATLANTA
STATE: GA ZIP: 30303
PHONE: BUSINESS PHONE:
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LIT TYPE: DEFENDANT SOC SEC NO:

——SERVICE——

CASE NO: 92VS0061273 SEQ NO: 01
DATE SENT: 08/07/92 DATE RECD:

RT/PTNR: 459 SERVICE DATE: 08/07/92
SERVICE TYPE: CORPORATION
LIT TYPE: DEFENDANT
NOTE: WESTINGHOUSE

CASE NO: 92VS0061273 SEQ NO: 02
DATE SENT: 08/10/92 DATE RECD:

RT/PTNR: 446 SERVICE DATE 08/10/92
SERVICE TYPE: CORPORATION
LIT TYPE: DEFENDANT
NOTE: GENERAL ELECTRIC COMPANY

CASE NO: 92VS0061273 SEQ NO: 03
DATE SENT: 08/10/92 DATE RECD:
RT/PTNR: 446 SERVICE DATE: 08/10/92
SERVICE TYPE: CORPORATION
LIT TYPE: DEFENDANT
NOTE: MONSANTO COMPANY

• • • •

——PLAINTIFF——

CASE NO: 9ZVS0061273 SEQ NO: 01
NAME: JOINER, ROBERT K
NAME DESC: SHORT NAME: JOINER, RO
COUNSEL: MICHAEL J WARSHAUER
COUNSEL TYPE:
LIT TYPE: PLTF

——DOCKET ENTRY——

CASE NO: 9ZVS0061273 DATE: 09/04/92
ACTION: ANSWER
LIT TYPE: DEFENDANT L/D SEQ:
EVENT RESULT:
NOTE: OF DEFT MONSANTO COMPANY

CASE NO: 9ZVS0061273 DATE: 09/04/92
ACTION: ANSWER
LIT TYPE: DEFENDANT L/D SEQ:
EVENT RESULT:
NOTE: OF DEFT. GENERAL ELECTRIC CO.

CASE NO: 9ZVS0061273 DATE: 09/04/92
ACTION: ANSWER
LIT TYPE: DEFENDANT L/D SEQ:
EVENT RESULT:
NOTE: OF DEFT. WESTINGHOUSE ELECTRIC CORP.

CASE NO: 9ZVS0061273 DATE: 09/04/92
ACTION: JURY—12 PERSON
LIT TYPE: DEFENDANT L/D SEQ:
EVENT RESULT:
NOTE: OF DEFT. GENERAL ELECTRIC CO

CASE NO: 9ZVS0061278 DATE: 09/04/92
ACTION: MOVE TO US DIS CT
LIT TYPE: DEFENDANT L/D SEQ:
EVENT RESULT:
NOTE: TO U.S. DIST COURT

• • • •

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Civil Docket for Case #: 92-CV-2137

JOINER, *et al.*

v.

GENERAL ELECTRIC CO. *et al.*

DOCKET ENTRIES

Date	No.	Proceedings
9/4/92	1	NOTICE OF REMOVAL with COMPLAINT.; jury demand (Pretrial instructions attached to service copies and returned to attorney for service.) FILING FEE $120.00 RECEIPT # 178048 (dt) [Entry date 09/09/92]
9/4/92	—	REMOVAL ANSWERS to complaint [1-1] by General Electric Co, Westinghouse Elec, Monsanto Company. Jury demand (dt) [Entry date 09/09/92]
9/10/92	2	Certificate of interested persons. (to judge) (dt) [Entry date 09/11/92]
10/27/92	3	ANSWER TO MANDATORY INTERROGATORIES by pltfs, Robert K. Joiner, Karen P. Joiner (dt) [Entry date 10/29/92]
11/9/92	4	Preliminary Statement and Scheduling Order. (to judge) (dt) [Entry date 11/12/92]
11/19/92	5	Notice of change of address by firm of Freeman & Hawkins. (dt) [Entry date 11/23/92]
11/20/92	6	Preliminary Statement and Scheduling Order. (to judge) (approved by Judge Evans on 12/1/92) (dt) [Entry date 11/24/92] [Edit date 12/04/92]

Date	No.	Proceedings
12/1/92	7	CONSENT ORDER extending time for dfts to respond to mandatory interr thru 12/11/92 by Judge Orinda D. Evans. cc (dt) [Entry date 12/04/92]
12/3/92	8	CONSENT ORDER approved by dep. clerk extending time thru 1/4/93 for dfts to respond to interr etc. cc (dt) [Entry date 12/09/92
12/11/92	9	ANSWER TO MANDATORY INTERROGATORIES by dft Monsanto Company (dt) [Entry date 12/14/92]
12/11/92	10	ANSWER TO MANDATORY INTERROGATORIES by dft Westinghous Elec. (dt) [Entry date 12/14/92]
12/11/92	11	ANSWER TO MANDATORY INTERROGATORIES by dft General Electric Co. (dt) [Entry date 12/14/92]
12/15/92	12	CONSENT ORDER extending time to 1/4/93 by Judge Orinda D. Evans. cc (dt) [Entry date 12/16/92]
1/4/93	13	Stipulation by parties extending time for dfts to respond to interr. thru 1/11/93 (dt) [Entry date 01/07/93]
1/21/93	14	MOTION by plaintiff Robert J. Joiner, plaintiff Karen P. disc. with brief in support. (dt) [Entry date 01/25/93]
1/29/93	15	Notice to take deposition of G. Frame, G. Maiuri, H. Pearce, E. Walsh, R. Barna, J. Aldworth, C. Murray, D. Keiser, R. Kelly, P. Cole, W. Waddell, W. Papageorge by defendant General Electric Co (dt) [Entry date 02/01/93]
2/1/93	16	Response by defendant General Electric Co, defendant Westinghouse Elec, defendant Monsanto Company in support of motion to extend time for disc. by Karen P. Joiner, Robert K. Joiner [14-1] (dt) [Entry date 02/02/93]

Date	No.	Proceedings
2/1/93	17	Application for leave of absence of Joanne Beauvoir Brown w/proposed order. to ct dep. (dt) [Entry date 02/02/93]
2/2/93	—	SUBMITTED on motion to extend time for disc. by Karen P. Joiner, Robert K. Joiner [14-1] to Judge Orinda D. Evans. (dt)
2/3/93	18	ORDER by ct dep. GRANTING leave of absence of Joanne Beauvoir Brown [17-1] for 2/10 to 2/17/93. cc (dt) [Entry date 02/04/93]
2/4/93	19	ORDER GRANTING motion to extend time for disc. by Karen P. Joiner, Robert K. Joiner [14-1] Discovery ends 6/4/93 by Judge Orinda D. Evans. cc (dt) [Entry date 02/05/93]
3/4/93	20	Notice to take deposition of G. Frame by plaintiff Robert K. Joiner, plaintiff Karen P. Joiner (dt) [Entry date 03/05/93]
4/2/93	21	Notice to take deposition of dfts by plaintiff Robert K. Joiner (dt) [Entry date 04/05/93]
4/2/93	22	SUPPLEMENTAL ANSWER TO MANDATORY INTERROGATORIES by Robert K. Joiner, Karen P. Joiner (dt) [Entry date 04/05/93]
6/1/93	23	JOINT REQUEST by parties to extend time for discovery thru 8/3/93. to ODE (bj) [Entry date 06/07/93]
6/10/93	24	CONSENT ORDER GRANTING motion to extend time for discovery thru 8/3/93 by Karen P. Joiner, Robert K. Joiner [21-1] by Judge Orinda D. Evans. cc (dt) [Entry date 06/15/93]
6/30/93	25	Notice to take deposition of D. Huckaby, J. McKinney, W. Mundy, R. Gladish, G. Coulter, R. Lester, G. Bowman by plaintiff Robert K. Joiner, plaintiff Karen P. Joiner (dt) [Entry date 07/01/93]

Date	No.	Proceedings
6/30/93	26	MOTION by plaintiff Robert K. Joiner, plaintiff Karen P. Joiner to extend time for disc. thru 10/31/93 with brief in support. (dt) [Entry date 07/01/93]
6/30/93	27	2nd Supplemental ANSWER TO MANDATORY INTERROGATORIES by pltfs Robert K. Joiner, Karen P. Joiner (dt) [Entry date 07/02/93]
7/6/93	28	MOTION by plaintiff Robert K. Joiner, plaintiff Karen P. Joiner for leave to amend removal complaint [1-1] with brief in support. (dt) [Entry date 07/07/93]
7/8/93	29	Notice to take deposition of Dr. Brown, Dr. Kelly, W. Papageorge by plaintiff Robert K. Joiner, plaintiff Karen P. Joiner (dt) [Entry date 07/09/93]
7/9/93	30	Joint MOTION by parties to extend time for disc. and for scheduling order with brief in support. to ODE (dt) [Entry date 07/13/93]
7/13/93	31	ORDER GRANTING joint motion to extend time for disc. and for scheduling order by Robert K. Joiner [30-1] by Judge Orinda D. Evans. cc (see same for scheduling—disc also stayed pending ruling on any motions in limine or s.j.). (dt) [Entry date 07/14/93]
7/22/93	32	Application for leave of absence of Michael J. Warshauer cc (dt) [Entry date 07/27/93]
7/22/93	33	ORDER by ct dep. GRANTING leave of absence of Michael J. Warshauer [32-1] for 7/29 to 8/16/93. cc (dt) [Entry date 07/27/93]
7/29/93	—	SUBMITTED on Motion for leave to amend removal complaint [1-1] by Karen P. Joiner, Robert K. Joiner [28-1] to Judge Orinda D. Evans. (dt)

Date	No.	Proceedings
8/4/93	34	ORDER GRANTING motion for leave to amend removal complaint [1-1] by Karen P. Joiner, Robert K. Joiner [28-1] by Judge Orinda D. Evans. cc (dt) [Entry date 08/05/93]
8/20/93	35	Stipulation by parties extending time thru 9/10/93 for dfts to respond to disc. being pltf's 2nd interr etc (dt) [Entry date 02/23/93]
8/24/93	36	AMENDED COMPLAINT [1-1] by Robert K. Joiner, Karen P. Joiner; jury demand. (dt) [Entry date 08/25/93]
9/1/93	37	EXPERT WITNESS designation by defendant Monsanto Company, defendant General Electric Co, defendant Westinghouse Elec (dt) [Entry date 09/02/93]
9/2/93	38	ANSWER to amended complaint [36-1] by Westinghouse Elec (dt) [Entry date 09/03/93]
9/2/93	39	ANSWER to amended complaint [36-1] by Monsanto Company (dt) [Entry date 09/03/93]
9/3/93	40	ANSWER to amended complaint [36-1] by General Electric Co (dt) [Entry date 09/07/93]
9/30/93	41	SECOND Notice to take deposition of W. Waddell, P. Cole by plaintiff Robert K. Joiner, plaintiff Karen P. Joiner (dt) [Entry date 10/01/93]
10/12/93	42	Notice of change of address by firm of Burge & Wettermark. . (dt) [Entry date 10/13/93]
10/19/93	43	SUPPLEMENTAL ANSWER TO MANDATORY INTERROGATORIES by dft Monsanto Company (dt) [Entry date 10/20/93]
10/21/93	44	Second Supplemental ANSWER TO MANDATORY INTERROGATORIES by dft Monsanto Company (dt) [Entry date 10/25/93]

Date	No.	Proceedings
12/7/93	45	CONSENT ORDER extending time for dfts to file motion for s.j thru 12/8/93 by Judge Orinda D. Evans. cc (dt) [Entry date 12/08/93]
12/8/93	46	JOINT MOTION by defendant General Electric Co, defendant Westinghouse Elec, defendant Monsanto Company for summary judgment and statement of material facts with brief in support. (dt) [Entry date 12/10/93]
12/8/93	47	MOTION (request) by defendant General Electric Co., defendant Westinghouse Elec, defendant Monsanto Company for oral argument on motion for s.j. with brief in support. (dt) [Entry date 12/10/93]
12/8/93	48	Notice of filing disc. in support of s.j. by defendant General Electric Co, defendant Westinghouse Elec, defendant Monsanto Company. (dt) [Entry date 12/10/93]
12/8/93	—	Deposition of T. Rouse, R. Joiner, D. Teitelbaum, L. Robertson, G. Frame, J. Brown taken in regards to s.j. for defendant General Electric Co, defendant Westinghouse Elec, defendant Monsanto Company (dt) [Entry date 12/10/93]
12/8/93	49	REQUEST for filing disc. material by defendant General Electric Co., defendant Westinghouse Elec, defendant Monsanto Company (dt) [Entry date 12/10/93]
12/10/93	—	Notice of motion for summary judgment, statement of material facts by Monsanto Company, Westinghouse Elec, General Electric Co [46-1] filed 12/8/93, mailed 12/10/93. (dt)
12/28/93	50	MOTION by plaintiff Robert K. Joiner, plaintiff Karen P. Joiner to extend time to 1/31/94 to respond to motion for summary judgment and statement of material facts by Monsanto Company, Westinghouse Elec, General Electric Co [46-1] with brief in support. (dt) [Entry date 01/03/94]

Date	No.	Proceedings
1/3/94	51	CONSENT ORDER approved by dep. clerk extending time for 1 week for pltf to respond to motion for summary judgment and statement of material facts by Company, Westinghouse Elec, General Electric Co [46-1]. cc (dt) [Entry date 01/05/94]
1/5/94	52	CONSENT ORDER GRANTING motion to extend time to 1/31/94 to respond to motion for summary judgment and statement of material facts by Monsanto Company, Westinghouse Elec, General Electric Co [46-1] by Karen P. Joiner, Robert K. Joiner [50-1] by Judge Orinda D. Evans. cc (dt) [Entry date 01/06/94]
1/31/94	53	Response by plaintiff Robert K. Joiner, plaintiff Karen J. Joiner w/affidavit in opposition to motion for summary judgment and Response to statement of material facts by Monsanto Company, Westinghouse Elec, General Electric Co [46-1] (dt) [Entry date 02/02/94]
1/31/94	54	REQUEST by plaintiff Robert K. Joiner, plaintiff Karen P. Joiner for dfts to file orig. disc. (dt) [Entry date 02/02/94]
1/31/94	55	MOTION (request) by plaintiff Robert K. Joiner, plaintiff Karen P. Joiner for oral argument on motion for s.j. [Entry date 02/02/94]
1/31/94	56	Notice of filing orig. disc. by plaintiff Robert K. Joiner, plaintiff Karen P. Joiner (dt) [Entry date 02/02/94]
1/31/94	—	Deposition of A. Schecter, W. Bailey, P. Cole, W. Waddell, S. Hamilton, W. Papageorge and 2 vol of medical records of pltf. Robert Joiner taken for plaintiff Robert K. Joiner, plaintiff Karen P. Joiner in regards to s.j. (dt) [Entry date 02/02/94]

Date	No.	Proceedings
2/7/94	—	SUBMITTED on motion for summary judgment and statement of material facts by Monsanto Company, Westinghouse Elec, General Electric Co [46-1], motion for oral argument on motion for s.j. by Monsanto Company, Westinghouse Elec, General Electric Co [47-1], motion for oral argument on motion for s.j. by Karen P. Joiner, Robert K. Joiner to Judge Orinda D. Evans (dt)
2/28/94	57	Joint Memorandum by dfts in REPLY to response to motion for summary judgment [46-1] w/appendix. (dt) [Entry date 03/03/94] [Edit date 03/03/94]
3/16/94	58	Notice of filing disc. material by dfts (dt) [Entry date 03/18/94]
6/16/94	59	MOTION by deft GE for leave to file supplemental brief [Entry date 6/20/94]
7/14/94	60	ORDER GRANTING motion for leave to file supplemental brief by General Electric Co [59-1] by Judge Orinda D. Evans. cc sent out by ct dep. (dt) [Entry date 07/21/94]
7/19/94	—	SUBMITTED on motion for leave to file supplemental brief by General Electric Co [59-1] to Judge Orinda D. Evans. (dt)
7/22/94	61	Application for leave of absence of Michael J. Warshauer (dt) [Entry date 07/25/94]
7/22/94	62	ORDER by ct dep. GRANTING leave of absence of Michael J. Warshauer [61-1] for 7/29 to 8/15/94. cc (dt) [Entry date 07/25/94]
7/25/94	63	Supplemental brief by dft General Electric to motion for summary judgment by dfts [46-1] (dt) [Entry date 08/02/94]
8/8/94	64	MOTION by pltfs for leave to file brief in response to GE's Suppl. brief (dt) [Entry date 08/10/94]

Date	No.	Proceedings
8/15/94	65	ORDER GRANTING motion for leave to file brief in response to GE's Suppl. brief by Robert K. Joiner [64-1] by Judge Orinda D. Evans. cc (dt) [Entry date 02/18/94]
8/29/94	66	Reply brief to supplemental brief by General Electric Co [63-1] by pltfs. (dt) [Entry date 08/30/94]
9/1/94	67	MOTION by dft General Electric Co for leave to file supplemental brief (dt) [Entry date 09/07/94]
9/13/94	68	Response by pltfs in opposition to motion for leave to file supplemental brief by General Electric Co [67-1] (dt) [Entry date 09/14/94]
9/16/94	69	ORDER GRANTING motion for summary judgment by Monsanto, Westinghouse, General Electric [46-1], DENYING motion for oral argument on motion for s.j. by Monsanto Company, Westinghouse Elec, General Electric Co [47-1], DENYING motion for oral on motion for s.j. by pltfs. [55-1], DENYING motion for leave to file supplemental brief by General Electric Co [67-1] by Judge Orinda D. Evans. cc (dt) [Entry date 09/20/94]
9/16/94	70	JUDGMENT ENTERED on amend/amended complaint [36-1], removal complaint [1-1] for dfts againts pltfs for costs of action. cc (dt) [Entry date 09/20/94]
9/27/94	71	NOTICE OF APPEAL from order [69-1], judgment. copy of dkt, NOA, order and judgment to USCA. Letter sent to counsel to pay fee. (dt) [Entry date 10/05/94]
10/13/94	—	USCA appeal fees received $105.00. r/209923. USCA notified (dt)
10/14/94	72	Bill of costs of defendant Westinghouse Elec. (dt) [Entry date 10/18/94]

Date	No.	Proceedings
10/14/94	73	Bill of costs of defendant General Electric Co. (dt) [Entry date 10/18/94]
10/14/94	74	Bill of costs of defendant Monsanto Company. (dt) [Entry date 10/18/94]
10/18/94	—	COSTS TAXED in the amount of $4,067.98 for defendant Westinghouse Elec against pla. (dt)
10/18/94	—	COSTS TAXED in the amount of $4,684.72 for defendant General Electric Co against pla. (dt)
10/18/94	—	COSTS TAXED in the amount of $4,548.74 for defendant Monsanto Company against pla. (dt)
10/18/94	—	Acknowledgment by Court of Appeals regarding appeal by Karen P. Joiner, Robert K. Joiner [71-1]. USCA dkt no. 94-9131 (jps) [Entry date 10/19/94]
11/1/94	—	Request for Certificate of Readiness from Court of Appeals regarding appeal. (fem) [Entry date 11/02/94]
11/9/94	—	CERTIFICATE OF READINESS OF RECORD ON APPEAL with certified copy of docket mailed to USCA. (5 vol. pleadings; 12 vol. depositions; 2 vol. medical records). (fem)
11/22/94	—	USCA acknowledges receipt of COR. (fem)
2/24/95	—	FORTHWITH LETTER from U.S. Court of Appeals regarding appeal. (oug) [Entry date 03/07/95]
2/28/95	—	Certified and TRANSMITTED RECORD to U.S. Court of Appeals appeal by Karen P. Joiner, Robert K. Joiner [71-1]. (5 vol. of pleadings, 12 depos. and 2 vols. of medical records). (oug) [Entry date 03/07/95]

Date	No.	Proceedings
6/12/96	75	Certified copy of ORDER of the U.S. Court of Appeals DENYING appellees petition for rehearing. cc (dt) [Entry date 6/20/96]
7/11/96	76	Certified copy of ORDER of the U.S. Court of Appeals GRANTING G.E.'s motion to stay mandate pending petition for writ of certiorari, cc (dt) [Entry date 07/12/96]
8/5/96	77	Certified copy of ORDER of the U.S. Court of Appeals GRANTING appellees' motion for ext. of time to stay issuance of mandate to 8/5/96. cc (dt) [Entry date 08/06/96]

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 94-9131

ROBERT K. JOINER, KAREN P. JOINER,
Plaintiffs-Appellants,

versus

GENERAL ELECTRIC COMPANY,
A New York Corporation;
WESTINGHOUSE ELECTRIC CORPORATION,
A Pennsylvania Corporation;
MONSANTO COMPANY,
A Delaware Corporation,
Defendants-Appellees.

DOCKET ENTRIES

Date	Proceedings
11/29/94	Civil Docketing Statement
10/17/94	Staff Atty. Jurisdiction
10/21/94	Probable Jurisdiction Noted
11/10/94	Certificate of Readiness due 11/18/94
3/1/95	ROA (# Vols. 5, p. 5, T —) due 1/06/95
3/1/95	Exhibits (Itemize) 2 boxes Depositions, Exhibits
	BRIEFING INFORMATION
1/17/95	Brief for Appellant D: 1/13 due 1/13/95
1/13/95	Record Excerpts
2/21/95	Brief for Appellee M3/1 D:2/21 due 2-20-95

Date	Proceedings
3/13/95	Reply Brief for Appellants 3-10-95
6/13/95	Supp. Authority Apt — Ape x
6/22/95	Supp. Authority Apt x Ape — CE'd to Panel
6/30/95	Supp. Auth. Ape x CE'd to panel
	OTHER MOTIONS & ORDERS
4/29/96	Flg. motion of appellant to file bill of costs out of time. dc
5/24/96	FLG. ORDER: Appellant's motion to file bill of costs out of time is GRANTED. (RB) (J) smg
6/18/96	Flg. Appellees' motion for stay of issuance of mandate. dc
6/20/96	Flg. response letter in opposition to stay more than 30 days. dc
7/9/96	Flg. ORDER that Motion of General Electric to Stay mandate pending certiorari to and including 7/18/96 is GRANTED/RB/. dc
7/15/96	Flg. unopposed motion to extend issuance of mandate pending certiorari. dc
8/2/96	Flg. ORDER that Motion of Appellees' for extension of time to stay the issuance of mandate to and including 8/5/96 is GRANTED/RB/. dc
	CALENDAR INFORMATION
4/2/95	Argument Scheduled for 6/13/95 in ATLANTA #339
	Argument Panel SFB/RB/SMITH
6/13/95	Case Argued—By Apt x By Ape x
	OPINION INFORMATION
3/27/96	Opinion issued
	RB signed SFB conc. spec. RE Smith dissent

Date	Proceedings
	JUDGMENT AND MANDATE INFORMATION
6/3/96	Bill of Costs Filed—Costs Awarded To
8/27/96	Judgment Entered
7/9/96	Mandate Stayed to 7/18/96/*8/5/96
	REHEARING INFORMATION
4/17/96	Petition for Rehearing M J
	Ape Panel En Banc
6/11/96	Order Denying Rehearing
	SUPREME COURT INFORMATION—NO. 96-188
8/9/96	Notice of Flg. Cert. on 8/5/96
12/5/96	Cert. Record Transmitted 5 vols/2 Bx-Exh.

IN THE STATE COURT OF FULTON
STATE OF GEORGIA

JURY TRIAL DEMANDED

Civil Action File No. 92-VS-61273A

ROBERT K. JOINER, and KAREN P. JOINER,
Plaintiffs,

v.

GENERAL ELECTRIC COMPANY,
a New York Corporation,
WESTINGHOUSE ELECTRIC CORPORATION,
a Pennsylvania Corporation,
and MONSANTO COMPANY,
a Delaware Corporation,
Defendants.

COMPLAINT

NOW COME Plaintiffs, and file this Complaint against Defendants as follows:

1.

Defendant, General Electric Company, a New York corporation, ("GE") maintains its registered agent in Fulton County, Georgia, committed a tortious act in Georgia, and is subject to the jurisdiction of the courts of this state, venue in this Court is proper, and it may be served with Summons and Complaint as allowed by law.

2.

Defendant, Westinghouse Electric Corporation, a Pennsylvania corporation ("Westinghouse") maintains its registered agent in Fulton County, Georgia, committed a tortious act in Georgia, and is subject to the jurisdiction of the courts of this state, venue in this Court is proper,

and it may be served with Summons and Complaint as allowed by law.

3.

Defendant, Monsanto Company, a Delaware corporation, ("Monsanto"), maintains its registered agent in Fulton County, Georgia, committed a tortious act in Georgia, and is subject to the jurisdiction of the courts of this state, venue in this Court is proper, and it may be served with Summons and Complaint as allowed by law.

4.

Defendant Monsanto manufactured Polychlorinated Biphenyls ("PCB") to be used in the manufacturing, testing and as a cooling fluid in electrical transformers manufactured by Defendants GE and Westinghouse.

5.

Defendants GE and Westinghouse manufactured and sold as new products electrical transformers containing PCB fluid manufactured by Defendant Monsanto.

6.

At the time of the manufacturing of these transformers with PCB fluid used in the manufacturing, testing and ultimate product, all Defendants were aware that PCBs were unreasonably dangerous and likely to cause injury and death to human beings who were exposed to the PCB fluids, including PCB residues in mineral oil fluids, during service and use of the transformer products.

7.

Plaintiff Robert K. Joiner was an ultimate, foreseeable, intended user and servicer of the transformer products manufactured by Defendants GE and Westinghouse which contained PCB fluids, and PCB contamination, manufactured by Defendant Monsanto.

8.

Throughout the course of his use of the transformers in his capacity as a repairman, Plaintiff Robert K. Joiner was caused to be exposed to PCB, was caused to be exposed to PCB fumes, and was caused to inhale PCB contaminated fluids, mists, liquids, and steams and he was also caused to absorb PCB through contact with his skin.

9.

As a result of Plaintiff Robert K. Joiner's exposure to PCBs, he contracted terminal lung cancer.

COUNT ONE
(STRICT LIABILITY AGAINST DEFENDANTS GE AND WESTINGHOUSE)

10.

Plaintiffs repeat, reallege, and incorporate by reference, the allegations of paragraphs 1 through 9 as if repeated herein as paragraph 10.

11.

Defendants put an unreasonably dangerous and defective product, the PCB contaminated electrical transformers, into the stream of commerce. The defect was the proximate cause of a serious bodily injury sustained by Plaintiff Robert K. Joiner. As a result, Defendants are strictly liable to Plaintiff.

12.

As a direct and proximate result of Defendants' acts, Plaintiff Robert K. Joiner was injured and suffered damages including permanent physical disfigurement, permanent physical disability, past pain and suffering, future pain and suffering, past medical expenses and lost wages, and future medical expenses and lost wages, all entitling him to an award of damages in his favor and against Defendants, and each of them, jointly and

severally, in an amount in excess of Ten Million Dollars ($10,000,000.00.)

COUNT TWO
(NEGLIGENCE AGAINST DEFENDANTS GE AND WESTINGHOUSE)

13.

Plaintiff repeats, realleges, and incorporates by reference, the allegations of paragraphs 1 through 12 as if repeated herein as paragraph 13.

14.

Defendants GE and Westinghouse negligently manufactured and distributed the electrical transformers in that: (i) the electrical transformers were sold in a condition which allowed it to be contaminated with PCBs and cause serious injury in expected use; (ii) the electrical transformers were defective in that they were manufactured and sold with PCB contamination which was likely to cause injury in the use for which they were intended; and (iii) the electrical transformers were sold without adequate warnings and instructions with respect to the known and unknown dangers of PCBs contained within them. This negligence was the proximate cause of a serious bodily injury sustained by Plaintiff.

15.

As a direct and proximate result of Defendant GE's and Westinghouse's negligence, Plaintiff was injured and has suffered damages including permanent physical disfigurement, permanent physical disability, past pain and suffering, future pain and suffering, past medical expenses and lost wages, and future medical expenses and lost wages, all entitling him to an award of damages in his favor and against Defendants, and each of them, jointly and severally, in an amount in excess of Ten Million Dollars ($10,000,000.00.)

COUNT THREE
(FRAUD AGAINST DEFENDANTS GE AND WESTINGHOUSE)

16.

Plaintiff repeats, realleges, and incorporates by reference, the allegations of paragraphs 1 through 15 as if repeated herein as paragraph 16.

17.

Defendants GE and Westinghouse represented to the buying public and those who serviced their electrical transformer products, including Plaintiff Robert K. Joiner, that the electrical transformer products were free from PCBs and were safe in regular use and servicing.

18.

Defendants GE and Westinghouse intended for the buying public and those who serviced their electrical transformer products, including Plaintiff Robert K. Joiner, to rely on their representations that the electrical transformer products were free from PCB and were safe in regular use and servicing.

19.

The buying public and those who serviced their electrical transformer products, including and particularly Plaintiff Robert K. Joiner, reasonably relied on the representations of Defendants GE and Westinghouse that the electrical transformer products were free from PCBs and were safe in regular use and servicing and as a result Plaintiff Robert K. Joiner took no precautions to protect himself when handling and servicing the electrical transformer products.

20.

As a direct and proximate result of the justifiable reliance on Defendant GE's and Westinghouse's fraudulent misrepresentations, Plaintiff Robert K. Joiner was exposed

to PCBs and was caused to contract terminal lung cancer and was otherwise injured and has suffered damages including permanent physical disfigurement, permanent physical disability, past pain and suffering, future pain and suffering, past medical expenses and lost wages, and future medical expenses and lost wages, all entitling him to an award of damages in his favor and against Defendants, and each of them, jointly and severally, in an amount in excess of Ten Million Dollars ($10,000,000.00.)

COUNT FOUR
(STRICT LIABILITY AGAINST DEFENDANT MONSANTO)

21.

Plaintiffs repeat, reallege, and incorporate by reference, the allegations of paragraphs 1 through 20 as if repeated herein as paragraph 21.

22.

Defendant Monsanto put an unreasonably dangerous and defective product, the PCB fluids, into the stream of commerce. The defect was the proximate cause of a serious bodily injury sustained by Plaintiff Robert K. Joiner. As a result, Defendants are strictly liable to Plaintiff.

23.

As a direct and proximate result of Defendant Monsanto's acts, Plaintiff Robert K. Joiner was injured and suffered damages including permanent physical disfigurement, permanent physical disability, past pain and suffering, future pain and suffering, past medical expenses and lost wages, and future medical expenses and lost wages, all entitling him to an award of damages in his favor and against Defendants, and each of them, jointly and severally, in an amount in excess of Ten Million Dollars ($10,000,000.00.)

COUNT FIVE
(NEGLIGENCE AGAINST DEFENDANT MONSANTO)

24.

Plaintiff repeats, realleges, and incorporates by reference, the allegations of paragraphs 1 through 23 as if repeated herein as paragraph 24.

25.

Defendant Monsanto negligently manufactured and distributed the PCB fluid in that: (i) the PCB fluid was unreasonably dangerous and known to be likely to cause serious injury in expected use; (ii) the PCB fluid was sold without adequate warnings and instructions with respect to the known and unknown dangers of PCBs. This negligence was the proximate cause of a serious bodily injury sustained by Plaintiff.

26.

As a direct and proximate result of Defendant Monsanto's negligence, Plaintiff was injured and has suffered damages including permanent physical disfigurement, permanent physical disability, past pain and suffering, future pain and suffering, past medical expenses and lost wages, and future medical expenses and lost wages, all entitling him to an award of damages in his favor and against Defendants, and each of them, jointly and severally, in an amount in excess of Ten Million Dollars ($10,000,000.00.).

COUNT SIX
(LOSS OF CONSORTIUM AGAINST ALL DEFENDANTS)

27.

Plaintiff repeats, realleges, and incorporates by reference, the allegations of paragraphs 1 through 26 as if repeated herein as paragraph 27.

28.

At all times relevant to this action, Plaintiff Karen P. Joiner has been the wife of Plaintiff Robert K. Joiner.

29.

As a direct and proximate result of the wrongful conduct of Defendants, and each of them, Plaintiff Robert K. Joiner suffered severe and permanent bodily injuries including serious and permanent physical and emotional injury and disability, substantial and continuing pain, suffering, and discomfort, and lost wages and medical expenses, both past and future. As a result of these injuries to her husband, Plaintiff Karen P. Joiner has lost the domestic and conjugal services previously provided to her by her husband and has been deprived of her right to consortium.

30.

As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Karen P. Joiner is entitled to an award of general damages for her loss of consortium in an amount to be determined by a jury of her peers in an amount in excess of Ten Million Dollars ($10,000,000.00.) against each of them, jointly and severally.

COUNT SEVEN
(PUNITIVE DAMAGES AGAINST ALL DEFENDANTS)

31.

Plaintiff repeats, realleges, and incorporates by reference, the allegations of paragraphs 1 through 30 as if repeated herein as paragraph 31.

32.

Defendants' conduct in defrauding Plaintiff is intentional, in bad faith, and in wanton disregard of Plaintiff's rights. Defendants' conduct in distributing and selling

defective and dangerous products which Defendants knew were likely to cause bodily injury was willful, wanton, and in callous disregard for human health and safety.

33.

As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs are entitled to judgment against Defendants, and each of them, jointly and severally, for exemplary damages to deter each of them from similar conduct in the future and to punish them for their wrongful acts in an amount to be determined by the enlightened conscience of the finder of fact in an amount in excess of Twenty Million Dollars ($20,000,000.00).

WHEREFORE, Plaintiff prays that summons issue, that Defendants be served and made to appear and answer, that a JURY TRIAL be held, and that they be awarded judgment in their favor and against the Defendants, jointly and severally, as follows:

(a) Under Count One, that Plaintiff Robert K. Joiner be awarded his special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00.);

(b) Under Count Two, that Plaintiff Robert K. Joiner be awarded his special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00.);

(c) Under Count Three, that Plaintiff Robert K. Joiner be awarded his special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00.);

(d) Under Count Four, that Plaintiff Robert K. Joiner be awarded his special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00.);

(e) Under Count Five, that Plaintiff Robert K. Joiner be awarded his special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00);

(f) Under Count Six, that Plaintiff Karen P. Joiner be awarded her special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00);

(g) Under Count Seven, that Plaintiffs be awarded punitive damages in an amount in excess of Twenty Million Dollars ($20,000,000.00.);

(h) That the cost of this action be levied against Defendants; and,

(i) That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Respectfully Submitted,

BURGE & WETTERMARK

By: /s/ Michael J. Warshauer
MICHAEL J. WARSHAUER
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[Filed Sep. 4, 1992]

IN THE STATE COURT OF FULTON COUNTY
STATE OF GEORGIA

(Title Omitted in Printing)

ANSWER OF GENERAL ELECTRIC COMPANY TO PLAINTIFFS' COMPLAINT

COMES NOW Defendant GENERAL ELECTRIC COMPANY (hereinafter "General Electric") and answers Plaintiff's Complaint as follows:

First Defense

General Electric answers the numbered paragraphs of the Complaint as follows:

1.

General Electric denies the allegations in this paragraph insofar as they allege that General Electric committed a tortious act in Georgia. For further answer to Paragraph 1 of the Complaint, General Electric admits that it is subject to the jurisdiction and venue of this Court.

2.

General Electric is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint.

3.

General Electric is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint.

4.

General Electric admits that Monsanto manufactured Polychlorinated Biphenyls ("PCB") to be used in electrical transformers manufactured by General Electric. General Electric also manufactured electrical transformers which did not contain PCB's, and therefore, General Electric is without knowledge or information sufficient to form a belief as to the allegation that Robert K. Joiner was exposed to PCB's. Except as thus stated, General Electric is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 4 of the Complaint.

5.

General Electric admits the allegations in paragraph 5 of the Complaint. General Electric also manufactured electrical transformers which did not contain PCB's, and therefore, General Electric is without knowledge or information sufficient to form a belief as to the allegation that Robert K. Joiner was exposed to PCB's.

6.

General Electric denies the allegations in Paragraph 6 of the Complaint.

7.

General Electric is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7 of the Complaint. General Electric also manufactured electrical transformers which did not contain PCB's, and therefore, General Electric is without knowledge or information sufficient to form a belief as to the allegation that Robert K. Joiner was exposed to PCB's.

8.

General Electric is without knowledge or information sufficient to form a belief as to the truth of the allega-

tions in Paragraph 8 of the Complaint. General Electric also manufactured electrical transformers which did not contain PCB's, and therefore, General Electric is without knowledge or information sufficient to form a belief as to the allegation that Robert K. Joiner was exposed to PCB's.

9.

General Electric denies the allegations in Paragraphs 9 of the Complaint.

10.

Answering Paragraph 10 of the Complaint, General Electric incorporates by reference its answers to Paragraphs 1 through 9 of the Complaint as if restated verbatim.

11.

General Electric denies the allegations in Paragraphs 11 of the Complaint.

12.

General Electric denies the allegations in Paragraphs 12 of the Complaint.

13.

Answering Paragraph 13 of the Complaint, General Electric incorporates by reference its answers to Paragraphs 1 through 12 of the Complaint as if restated verbatim.

14.

General Electric denies the allegations in Paragraphs 14 of the Complaint.

15.

General Electric denies the allegations in paragraph 15 of the Complaint.

16.

Answering Paragraph 16 of the Complaint, General Electric incorporates by reference its answers to Para-

graphs 1 through 15 of the Complaint as if restated verbatim.

17.

General Electric denies the allegations in paragraph 17 of the Complaint insofar as they suggest that any representations made by General Electric were false or misleading. General Electric is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 17 of Complaint regarding Robert K. Joiner.

18.

General Electric denies the allegations in Paragraph 18 insofar as they suggest that any representations made by General Electric were false or misleading. General Electric is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18 of Complaint regarding Robert K. Joiner.

19.

General Electric denies the allegations in paragraph 19 of the Complaint insofar as they suggest that any representations made by General Electric were false or misleading. General Electric is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19 of Complaint regarding Robert K. Joiner.

20.

General Electric denies the allegations in paragraph 20 of the Complaint.

21.-26.

The allegations of Paragraphs 21 through 26 of the Complaint require no answer by General Electric since it is not a party to Counts Four and Five of the Complaint. However, General Electric specifically denies that any claim for injuries or damages referenced in these paragraphs was caused by General Electric. To the

extent that these allegations require a further answer, General Electric denies the allegations of Paragraphs 21, 22, 23, 24, 25, and 26 of the Complaint.

27.

Answering Paragraph 27 of the Complaint, General Electric incorporates by reference its answers to Paragraphs 1 through 26 of the Complaint as if restated verbatim.

28.

General Electric is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 of Complaint.

29.

General Electric denies the allegations in Paragraph 29 of the Complaint.

30.

General Electric denies the allegations in Paragraph 30 of the Complaint.

31.

Answering Paragraph 31 of the Complaint, General Electric incorporates by reference its answers to Paragraph 1 through 30 of the Complaint as if restated verbatim.

32.

General Electric denies the allegations in Paragraph 32 of the Complaint.

33.

General Electric denies the allegations in Paragraph 33 of the Complaint.

34.

General Electric denies all other allegations in the Complaint to which specific reference has not been made in this answer.

ADDITIONAL DEFENSES

As there are no averments of time and place, as required by O.C.G.A. § 9-11-9(f), General Electric is required to answer the Complaint by raising affirmative defenses which may, or may not, be applicable, depending upon the facts and circumstances. As such, General Electric pleads the defenses which follow; however, General Electric reesrves the right to seasonably amend or supplement its answer upon discovery of facts and circumstances which give rise to additional defenses:

Second Defense

Plaintiff's Complaint, in whole or in part, fails to state a claim against General Electric upon which relief can be granted.

Third Deefnse

Plaintiff Robert K. Joiner's alleged injuries and damages, if as alleged, were not proximately caused by exposure to PCB's.

Fourth Defense

Plaintiff Robert K. Joiner's alleged injuries and damages, if as alleged, were not proximately caused by General Electric.

Fifth Defense

Some or all of Plaintiffs' claims may be barred by the applicable statute of repose; however, there are no allegations of time as required by O.C.G.A. § 9-11-9(f).

Sixth Defense

Some or all of Plaintiffs' claims may be barred by the applicable statute of limitations; however, there are no allegations of time as required by O.C.G.A. § 9-11-9(f).

Seventh Defense

Plaintiffs may be barred from recovery under the doctrine of assumption of the risk.

Eighth Defense

Plaintiffs may be barred from recovery, in whole or in part, due to Robert K. Joiner's negligence, under the doctrines of contributory and comparative negligence.

Ninth Defense

The fraud alleged in Count Three, Paragraphs 16-20, of the Complaint, are not stated with particularity as required by O.C.G.A. § 9(b).

Tenth Defense

Plaintiffs have failed to specifically state items of special damages as required by O.C.G.A. § 9-11-9(g).

Eleventh Defense

If Robert K. Joiner, by the exercise of ordinary care, could have avoided the consequences allegedly caused by General Electric's negligence, then the Plaintiffs are not entitled to recover.

Twelfth Defense

If neither Robert K. Joiner nor General Electric were guilty of negligence, then any injuries or damages would be the result of an accident.

Thirteenth Defense

Plaintiffs' claims for punitive damages are in violation of and barred by the due process clauses of the Georgia and United States Constitutions.

Fourteenth Defense

Plaintiffs' claims for punitive damages are in violation of and barred by the equal protection clauses of the Georgia and United States Constitutions.

WHEREFORE, having fully answered the Complaint, Defendant General Electric demands judgment in its favor as follows:

(1) Dismissing the Complaint with prejudice;

(2) Awarding all costs of litigation to Defendant General Electric; and

(3) Awarding all such other relief to Defendant General Electric as this Court deems proper.

This 4th day of September, 1992.

CHILIVIS & GRINDLER

/s/ Anthony L. Cochran
GARY G. GRINDLER—312650
ANTHONY L. COCHRAN—172425
TIMOTHY J. BUCKLEY, III—092913

Attorneys for General Electric Company

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IN THE STATE COURT OF FULTON
STATE OF GEORGIA

(Title Omitted in Printing)

ANSWER OF THE DEFENDANT, MONSANTO COMPANY

Comes now MONSANTO COMPANY, (hereinafter "MONSANTO"), Defendant in the above-styled cause, and for Answer to Plaintiffs' Complaint shows the following:

FIRST DEFENSE

In answer to the numbered paragraphs of Plaintiffs' Complaint, Defendant MONSANTO says:

1.

This Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph One (1) of Plaintiffs' Complaint.

2.

This Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph Two (2) of Plaintiffs' Complaint.

3.

With respect to the allegations contained in Paragraph Three (3) of Plaintiffs' Complaint, this Defendant denies that MONSANTO has committed a tortious act in Georgia but admits the remaining allegations contained in Paragraph Three (3).

4.

MONSANTO admits that from time to time it manufactures polychlorinated biphenyls which were sold to General Electric Corporation, among others, as cooling fluid in electrical transformers.

5.

The allegations contained in Paragraph Five (5) of Plaintiffs' Complaint are admitted.

6.

The allegations contained in Paragraph Six (6) of Plaintiffs' Complaint are denied.

7.

The allegations contained in Paragraph Seven (7) of Plaintiffs' Complaint are denied.

8.

The allegations contained in Paragraph Eight (8) of Plaintiffs' Complaint are denied.

9.

The allegations contained in Paragraph Nine (9) of Plaintiffs' Complaint are denied.

COUNT ONE

10.

In response to the allegations contained in Paragraph Ten (10) of COUNT ONE of Plaintiffs' Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answer to the allegations contained in Paragraphs 1 through 9.

11.

The allegations contained in Paragraph Eleven (11) of COUNT ONE of Plaintiffs' Complaint are denied.

12.

The allegations contained in Paragraph Twelve (12) of COUNT ONE of Plaintiffs' Complaint are denied.

COUNT TWO

13.

In response to the allegations contained in Paragraph Thirteen (13) of COUNT TWO of Plaintiffs' Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 12.

14.

The allegations contained in Paragraph Fourteen (14) of COUNT TWO of Plaintiffs' Complaint require no answer of the Defendant MONSANTO.

15.

The allegations contained in Paragraph Fifteen (15) of COUNT TWO of Plaintiffs' Complaint require no answer of the Defendant MONSANTO.

COUNT THREE

16.

In response to the allegations contained in Paragraph Sixteen (16) of COUNT THREE of Plaintiffs' Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 15

17.

The allegations contained in Paragraph Seventeen (17) of COUNT THREE of Plaintiffs' Complaint require no answer of the Defendant MONSANTO.

18.

The allegations contained in Paragraph Eighteen (18) of COUNT THREE of Plaintiffs' Complaint require no answer of the Defendant MONSANTO.

19.

The allegations contained in Paragraph Nineteen (19) of COUNT THREE of Plaintiffs' Complaint require no answer of the Defendant MONSANTO.

20.

The allegations contained in Paragraph Twenty (20) of COUNT THREE of Plaintiffs' Complaint require no answer of the Defendant MONSANTO.

COUNT FOUR

21.

In response to the allegations contained in Paragraph Twenty-one (21) of COUNT FOUR of Plaintiffs Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 20.

22.

The allegations contained in Paragraph Twenty-two (22) of COUNT FOUR of Plaintiffs' Complaint are denied.

23.

The allegations contained in Paragraph Twenty-three (23) of COUNT FOUR of Plaintiffs' Complaint are denied.

COUNT FIVE

24.

In response to the allegations contained in Paragraph Twenty-four (24) of COUNT FIVE of Plaintiffs' Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 23

25.

The allegations contained in Paragraph Twenty-five (25) of COUNT FIVE of Plaintiffs' Complaint are denied.

26.

The allegations contained in Paragraph Twenty-six (26) of COUNT FIVE of Plaintiffs' Complaint are denied.

COUNT SIX

27.

In response to the allegations contained in Paragraph Twenty-seven (27) of COUNT SIX of Plaintiffs' Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 26.

28.

This Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph Twenty-eight (28) of COUNT SIX of Plaintiffs' Complaint.

29.

The allegations contained in Paragraph Twenty-nine (29) of COUNT SIX of Plaintiffs' Complaint are denied.

30.

The allegations contained in Paragraph Thirty (30) of COUNT SIX of Plaintiffs' Complaint are denied.

COUNT SEVEN

31.

In response to the allegations contained in Paragraph Thirty-one (31) of COUNT SEVEN of Plaintiffs' Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 30.

32.

The allegations contained in Paragraph Thirty-two (32) of COUNT SEVEN of Plaintiffs' Complaint are denied.

33.

The allegations contained in Paragraph Thirty-three (33) of COUNT SEVEN of Plaintiffs' Complaint are denied.

SECOND DEFENSE

The Defendant MONSANTO COMPANY hereby denies any paragraph or any portion of any paragraph not previously referred to herein.

PREAMBLE TO AFFIRMATIVE DEFENSES

The Defendant MONSANTO COMPANY reserves the right to rely upon any of the following defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or by evidence at trial:

THIRD DEFENSE

No act or omission on the part of the Defendant MONSANTO either proximately caused or contributed to any injury alleged to have been sustained by Plaintiffs.

FOURTH DEFENSE

Upon information and belief, this Defendant says that Plaintiff ROBERT K. JOINER assumed the risk of injury, if any he sustained, himself and therefore is not entitled to recover of this Defendant.

FIFTH DEFENSE

Defendant MONSANTO says that, even if it was negligent in the manner set out and charged in the Complaint, which alleged negligence is expressly denied, the negligence of Plaintiff ROBERT K. JOINER was equal to or greater than any negligence charged against this Defendant in such Complaint and the consequences of such negligence, if any in fact existed, could have been avoided had ROBERT K. JOINER been in the exercise of ordinary care.

SIXTH DEFENSE

Upon information and belief, Plaintiff ROBERT K. JOINER has failed, in whole or in part, to mitigate and/or avoid any alleged injury purportedly sustained by Plaintiffs.

SEVENTH DEFENSE

Plaintiffs' claims for punitive damages are in violation of and barred by the due process clause of the 1983 Georgia Constitution, Article 1, Section 1, Paragraph 1, and by the Fifth and Fourteenth Amendments to the United States Constitution.

EIGHTH DEFENSE

Plaintiffs' claims for punitive damages are in violation of and barred by the equal protection clause of the 1983 Georgia Constitution, Article 1, Section 1, Paragraph 2, and by the Fourteenth Amendment to the United States Constitution.

NINTH DEFENSE

Upon information and belief, if Plaintiff ROBERT K. JOINER was exposed to polychlorinated biphenyls

("PCBs") alleged to have been manufactured by MONSANTO and if Plaintiff ROBERT K. JOINER incurred any injury resulting therefrom, all of which is expressly denied, Plaintiff ROBERT K. JOINER's injury would not have occurred but for the fact that the "PCBs" were materially changed or altered by Plaintiff ROBERT K. JOINER or others, whether or not such others are parties to this action, and such material change or alteration was not made in accordance with the instructions of MONSANTO, was not made with the consent of MONSANTO or was not the result of conduct that reasonably should have been anticipated by MONSANTO, and therefore Plaintiff ROBERT K. JOINER's claim is barred.

TENTH DEFENSE

Upon information and belief, if Plaintiff ROBERT K. JOINER sustained any injury or damage as alleged in the Complaint, which is denied, such injury was due to, caused by or contributed to, in whole or in part, to the negligence or carelessness of other parties over whom Monsanto had no control and for whose conduct MONSANTO is not responsible. Such negligence of other parties was the sole proximate cause of, or an intervening, superseding, or insulating cause of the Plaintiffs' alleged damages.

ELEVENTH DEFENSE

Upon information and belief, it is alleged that the Plaintiff ROBERT K. JOINER's employer at the time of the alleged exposure to "PCBs" was negligent in that the employer failed properly and safely to equip the Plaintiff ROBERT K. JOINER with the necessary protection; that the employer provided the orders and directions under which the Plaintiff ROBERT K. JOINER worked with or in the area of "PCBs" (if he did so); that the employer allowed "PCBs" to be used by the Plaintiff ROBERT K. JOINER and others in a manner so as to create a condition of danger for the Plaintiff ROBERT K. JOINER; that

although the employer knew or should have known in the exercise of ordinary care of the general requirements of the handling of "PCBs", the employer nevertheless failed to relate all such information to the Plaintiff ROBERT K. JOINER; that the employer failed to provide a safe place for the Plaintiff ROBERT K. JOINER to work; that the employer failed to provide suitable training and education for its employees, including the Plaintiff ROBERT K. JOINER; that the employer failed to require the Plaintiff ROBERT K. JOINER and others to keep the premises and their persons clean and in a normal state of good housekeeping and cleanliness. If the Plaintiff ROBERT K. JOINER sustained any injury or damage as set forth in the Complaint, which is denied, the same was directly and proximately caused by the foregoing negligence of the Plaintiff ROBERT K. JOINER's employer and such negligence was the sole proximate cause of or an intervening, superseding or insulating cause of the Plaintiff ROBERT K. JOINER's injury and damage, if any.

TWELFTH DEFENSE

Any purchaser or user who purchased or used "PCBs" alleged to have been manufactured by MONSANTO, as the developers and manufacturers of the final product to which the Plaintiff ROBERT K. JOINER was allegedly exposed, were sophisticated and knowledgeable users of "PCBs" and were in a far better position to instruct or warn Plaintiff ROBERT K. JOINER and, if any such instruction or warning was legally required, which is denied, their failure to instruct or warn the Plaintiff ROBERT K. JOINER was an intervening, superseding or insulating proximate cause of Plaintiff ROBERT K. JOINER's alleged injuries.

THIRTEENTH DEFENSE

If Plaintiff ROBERT K. JOINER was exposed to any "PCBs" alleged to have been manufactured by MONSANTO and if Plaintiff ROBERT K. JOINER incurred

any injury resulting therefrom, all of which is expressly denied, Plaintiff ROBERT K. JOINER's claim is barred by the applicable statute of limitations.

WHEREFORE, the Defendant MONSANTO COMPANY respectfully demands that judgment be rendered in its favor.

FREEMAN & HAWKINS

/s/ Joe C. Freeman, Jr.
JOE C. FREEMAN, JR.
Ga. State Bar No. 275700

/s/ Joanne Beauvoir Brown
JOANNE BEAUVOIR BROWN
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IN THE STATE COURT OF FULTON COUNTY
STATE OF GEORGIA

(Title Omitted in Printing)

ANSWER OF DEFENDANT WESTINGHOUSE ELECTRIC CORPORATION

COMES NOW defendant Westinghouse Electric Corporation and hereby raises its defenses and answers plaintiffs' complaint as follows:

FIRST DEFENSE

Plaintiffs' complaint fails to state a claim upon which relief may be granted.

SECOND DEFENSE

Plaintiffs' complaint is barred by the statute of limitations.

THIRD DEFENSE

Plaintiffs' complaint is barred by the statute of repose.

FOURTH DEFENSE

Plaintiffs are barred from any recovery under the doctrine of assumption of risk.

FIFTH DEFENSE

Plaintiffs are barred from any recovery in whole or in part by the contributory negligence or comparative fault of plaintiffs.

SIXTH DEFENSE

The allegations of fraud set forth in count three, paragraphs 16-20, of the plaintiff's complaint, are not stated with the requisite particularity.

SEVENTH DEFENSE

The plaintiffs have failed to specifically state items of special damages.

EIGHTH DEFENSE

Having raised its affirmative defenses and without waiving said defenses, defendant Westinghouse responds to each and every paragraph of the plaintiffs' complaint as follows:

1.

Defendant Westinghouse is without sufficient knowledge or information upon which to form a belief as to the truth or accuracy of the allegations contained in paragraph 1 of the complaint.

2.

Defendant Westinghouse admits that it is a Pennsylvania corporation, that it maintains a registered agent in Fulton County, Georgia, and that it is subject to the jurisdiction and venue of this Court. Defendant Westinghouse denies that it committed a tortious act in Georgia as alleged in plaintiffs' complaint and denies all remaining allegations of paragraph 2 of the plaintiffs' complaint.

3.

Defendant Westinghouse is without sufficient knowledge or information upon which to form a belief as to the truth or accuracy of the allegations contained in paragraph 3 of the complaint.

4.

Defendant Westinghouse admits that it purchased from Monsanto Company quantities of polychlorinated biphenyls for use in certain electrical transformers it manufactured. Defendant Westinghouse denies the remaining allegations of paragraph 4 of plaintiffs' complaint.

5.

Defendant Westinghouse admits that it was a manufacturer of electrical transformers which contained polychlorinated biphenyls and that some of these transformers contained polychlorinated biphenyls purchased from Monsanto Company. Defendant Westinghouse is without sufficient knowledge or information upon which to form a belief as to the truth or accuracy of the plaintiffs' allegations concerning General Electric Company.

6.

Defendant Westinghouse denies the allegations contained in paragraph 6 of the complaint.

7.

Defendant Westinghouse denies the allegations contained in paragraph 7 of the complaint.

8.

Defendant Westinghouse denies the allegations contained in paragraph 8 of the complaint.

9.

Defendant Westinghouse denies the allegations contained in paragraph 9 of the complaint.

10.

In response to paragraph 10 of plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein

its responses to paragraphs 1 through 9 of the complaint with the same force and effect as if they had been restated herein.

11.

Defendant Westinghouse denies the allegations contained in paragraph 11 of the complaint.

12.

Defendant Westinghouse denies the allegations contained in paragraph 12 of the complaint.

13.

In response to paragraph 13 of plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 12 of the complaint with the same force and effect as if they had been restated herein.

14.

Defendant Westinghouse denies the allegations contained in paragraph 14 of the complaint.

15.

Defendant Westinghouse denies the allegations contained in paragraph 15 of the complaint.

16.

In response to paragraph 16 of plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 15 of the complaint with the same force and effect as if they had been restated herein.

17.

Defendant Westinghouse denies the allegations contained in paragraph 17 of the complaint.

18.

Defendant Westinghouse denies the allegations contained in paragraph 18 of the complaint.

19.

Defendant Westinghouse denies the allegations contained in paragraph 19 of the complaint.

20.

Defendant Westinghouse denies the allegations concontained in paragraph 20 of the complaint.

21.

In response to paragraph 21 of plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 20 of the complaint with the same force and effect as if they had been restated herein.

22.

Defendant Westinghouse denies the allegations contained in paragraph 22 of the complaint.

23.

Defendant Westinghouse denies the allegations contained in paragraph 23 of the complaint.

24.

In response to paragraph 24 of plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 23 of the complaint with the same force and effect as if they had been restated herein.

25.

Defendant Westinghouse denies the allegations contained in paragraph 25 of the complaint.

26.

Defendant Westinghouse denies the allegations contained in paragraph 26 of the complaint.

27.

In response to paragraph 27 of plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 26 of the complaint with the same force and effect as if they had been restated herein.

28.

Defendant Westinghouse is without sufficient knowledge or information upon which to form a belief as to the truth or accuracy of the allegations contained in paragraph 28 of the complaint.

29.

Defendant Westinghouse denies the allegations contained in paragraph 29 of the complaint.

30.

Defendant Westinghouse denies the allegations contained in paragraph 30 of the complaint.

31.

Defendant Westinghouse is without sufficient knowledge or information upon which to form a belief as to the truth or accuracy of the allegations contained in paragraph 31 of the complaint.

32.

Defendant Westinghouse denies the allegations contained in paragraph 32 of the complaint.

33.

Defendant Westinghouse denies the allegations contained in paragraph 33 of the complaint.

WHEREFORE, having asserted its affirmative defenses and having answered plaintiffs' complaint, defendant Westinghouse demands judgment that the plaintiffs' complaint be dismissed with all costs cast against plaintiffs.

This the 4th day of September, 1992.

/s/ David H. Flint
DAVID H. FLINT
Georgia Bar No. 264600
ALEX J. SIMMONS, JR.
Georgia Bar No. 646990

Attorneys for defendant
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[Filed Sep. 4, 1992]

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Civil Action File No. 1 92.CV.2137

ROBERT K. JOINER, and
KAREN P. JOINER,
Plaintiffs

vs.

GENERAL ELECTRIC COMPANY,
A New York Corporation;
WESTINGHOUSE ELECTRIC CORPORATION,
a Pennsylvania corporation;
and MONSANTO COMPANY,
a Delaware corporation,
Defendants

PETITION FOR REMOVAL

The petition of GENERAL ELECTRIC COMPANY, WESTINGHOUSE ELECTRIC CORPORATION and MONSANTO COMPANY for the removal of the action herein referred to from the State Court of Fulton County, Georgia, to the United States District Court for the Northern District of Georgia, Atlanta Division, respectfully shows to the Court the following:

1.

That Petitioners herein, GENERAL ELECTRIC COMPANY, WESTINGHOUSE ELECTRIC CORPORATION and MONSANTO COMPANY, are Defendants in a civil action brought in the State Court of Fulton County,

Georgia, entitled *Robert K. Joiner, and Karen P. Joiner vs. General Electric Company, a New York Corporation, Westinghouse Electric Corporation, a Pennsylvania Corporation, and Monsanto Company, a Delaware Corporation,* Civil Action No. 92 VS 61273A. Attached hereto and made a part hereof are:

1. Exhibit "A"—A true copy of the original Summons & Complaint filed by Plaintiffs in the State Court of Fulton County, Georgia;

2. Exhibit "B"—A true copy of the Answer filed in the State Court of Fulton County, Georgia by Defendant WESTINGHOUSE ELECTRIC CORPORATION;

3. Exhibit "C"—Notice of Removal filed in the State Court of Fulton County, State of Georgia, by Petitioners.

4. Exhibit "D"—A true copy of the Answer filed in the State Court of Fulton County, Georgia by Defendant GENERAL ELECTRIC COMPANY;

5. Exhibit "E"—A true copy of the Answer filed in the State Court of Fulton County, Georgia by Defendant MONSANTO COMPANY;

The attachments hereto, Exhibits "A" "B" "C" "D" and "E" constitute all of the pleadings which have now been filed in the subject case in the said State Court of Fulton County.

2.

That said action was commenced by service upon Defendant WESTINGHOUSE ELECTRIC CORPORATION, through Prentice Hall Corporation System on August 7, 1992 and upon Defendants MONSANTO COMPANY and GENERAL ELECTRIC COMPANY, through C. T. Corporation System on August 10, 1992. This petition is filed within thirty (30) days from the date of service upon these Defendants in this case, pursuant to 28 USC § 1446.

3.

That the controversy between the Plaintiffs and your Petitioners is a controversy between residents of the State of Georgia and three corporations, residents of the States of New York, Pennsylvania and Missouri respectively.

4.

That upon information and belief, Plaintiffs, ROBERT K. JOINER and KAREN P. JOINER, were, at the time of the commencement of this action, and still are citizens and residents of the state of Georgia;

5.

Defendant GENERAL ELECTRIC COMPANY, a New York corporation was, at the time of the commencement of this action, and still is a corporation with its principal place of doing business located at Fairfield, Connecticut.

6.

Defendant WESTINGHOUSE ELECTRIC CORPORATION, a Pennsylvania corporation was, at the time of the commencement of this action, and still is, a corporation with its principal place of doing business located at Pittsburgh, Pennsylvania.

7.

Defendant MONSANTO COMPANY, a Delaware corporation, was at the time of the commencement of this action, and still is, a corporation with its principal place of doing business located at St. Louis, Missouri.

8.

That the matter in controversy exceeds the value of Fifty Thousand Dollars ($50,000.00) exclusive of interest and costs, and is a civil action brought in a State Court of the State of Georgia, of which the United States District Courts have original jurisdiction because of diver-

sity of citizenship and the amount in controversy pursuant to 28 USC § 1332.

6.

That the pending action is one which Defendants, GENERAL ELECTRIC CORPORATION, WESTINGHOUSE ELECTRIC CORPORATION and MONSANTO COMPANY, are entitled to remove to this Court pursuant to 28 USC § 1441.

WHEREFORE, Petitioners pray that this Petition for Removal be filed and that said action be removed to and proceed in this Court and that no further proceedings be had in the said case in the State Court of Fulton County, Georgia.

[Counsel omitted in printing.]

[Filed Oct. 27, 1992]

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

PLAINTIFFS' ANSWERS TO MANDATORY INTERROGATORIES

* * * *

EXPERT WITNESSES

* * * *

12) Dr. Larry W. Robertson, Associate Professor of Toxicology, Graduate Center for Toxicology, University of Kentucky, 204 Funkhouser Boulevard, Lexington, Kentucky 40506-0054. Dr. Robertson is expected to testify as to medical causation, specifically, that Plaintiff Robert K. Joiner's exposure to PCBs is a direct and proximate cause of his lung cancer. Dr. Robertson will also attest to his analysis of Triangle Laboratories' data and toxicology reports concerning the presence of PCBs in Plaintiff Robert K. Joiner's fat tissue. Dr. Robertson's testimony may be introduced by deposition.

As discovery is ongoing, Plaintiffs reserve the right to supplement their Witness List.

* * * *

[Filed in Chambers 7/9/93]

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

JOINT REQUEST FOR CONTINUANCE AND FOR SCHEDULING ORDER

All of the parties having consented, they collectively request that this Court extend the time for discovery and enter a scheduling order for the following reasons:

This is a tort action in which Robert and Karen Joiner contend that his lung cancer was caused by alleged exposure to certain chemicals. The Defendants deny liability for a number of reasons; however, the central issues in this case relate to causation of Robert K. Joiner's illness. As the Court would expect, the Plaintiffs and Defendants vigorously disagree over the issue of causation. While there are innumerable issues which could get litigated and discovered in this case (at great expense), there is one potentially dispositive issue, *i.e.*, causation of Robert K. Joiner's illness.

Causation must be established by expert testimony, *i.e.*, toxicologists, epidemiologists, analytical chemists and physicians in various specialties. It is appropriate for the Court to consider the proposed scheduling order in the interests of judicial economy. Additionally, the parties would hope to avoid unnecessary fees and expenses by first having this Court consider whether there is an issue of fact on the potentially dispositive issue of causation. A scheduling order addressing the issue of causation can be addressed first and resolved before the parties engage in expensive discovery and litigation on numerous other issues.

* * * *

The following facts support the requested extension and scheduling order:

1.

This case was removed to federal court on September 4, 1992.

2.

On October 26, 1992, the plaintiffs served their answers to the Court's mandatory interrogatories.

3.

In the plaintiffs' mandatory interrogatory answers, they identified one expert witness on the issue of medical causation, Dr. Larry W. Robertson, a toxicologist.

4.

On December 11, 1992, the defendants served their answers to the Court's mandatory interrogatories. At that time, the defendants identified several expert witnesses whose testimony will touch on the issue of medical causation: Dr. Philip Cole, Chairman of Department Epidemiology in the School of Public Health and Associate Director for Epidemiology of the Comprehensive Cancer Center at the University of Alabama at Birmingham; Dr. William J. Waddell, Chairman of the Department of Pharmacology and Toxicology at the University of Louisville School of Medicine; Dr. George Frame, a Research Scientist and Analytical Chemist with General Electric.

5.

On January 8, 1993, in interrogatory answers, General Electric identified Dr. Stephen B. Hamilton, Jr., Manager Science and Technology with General Electric as an additional expert with knowledge concerning research and testing conducted or sponsored by General Electric relating to PCB exposure among humans.

6.

On February 1, 1993, the parties consented to an extention of the discovery period through June 4 as additional time was necessary for the completion of discovery as a result of the Thanksgiving, Christmas and New Year's holidays.

7.

On April 1, 1993, the plaintiffs served their first supplemental response to this Court's mandatory interrogatories identifying Dr. Arnold J. Schecter as an additional expert witness on the issue of causation.

8.

On June 1, 1993, an additional extension of time was jointly requested by the parties to extend the discovery period due to complications in scheduling and other circumstances beyond the parties' control. The discovery period was extended through August 3, 1993.

9.

On June 9, 1993, the depositions of Robert and Karen Joiner were taken in Thomasville, Georgia.

10.

On June 23, 1993, the defendants supplemented their discovery responses identifying Dr. William C. Bailey, a Professor of Medicine at the University of Alabama School of Medicine in Birmingham, Alabama as an additional expert witness on the issue of causation.

11.

On June 29, 1993, the plaintiffs filed a motion to extend discovery through October 31, 1993.

12.

On June 30, 1993 the plaintiffs served their second supplemental response to this Court's mandatory interrog-

atories identifying two additional expert witnesses on the issue of causation: Dr. Daniel T. Teitelbaum, a Clinical Toxicologist, and Dr. Arthur L. Frank, a professor in the Department of Preventive Medicine and Environmental Health at the University of Kentucky College of Medicine.

13.

Depositions of the following witnesses are currently scheduled:

a. Dr. Robertson's deposition is currently scheduled for July 13 in Lexington, Kentucky;

b. Dr. Schecter's deposition in Binghamton, New York was originally scheduled for July 16 but was recheduled for July 14 at Dr. Schecter's request;

c. The deposition of Dr. Thomas O. Rouse of General Electric is currently scheduled for Tuesday, July 20, 1993 in Albany, New York;

d. The deposition of Mr. William Papageorge of Monsanto is scheduled for July 22, 1993 in St. Louis, Missouri;

e. The depositions of Drs. Frame and John F. Brown, Jr. of General Electric are scheduled for July 26, 1993 in Albany, New York;

f. The deposition of Dr. Stephen B. Hamilton, Jr., of General Electric, is scheduled for July 28, 1993 in Trumbull, Connecticut;

g. The deposition of Dr. Bailey is tentatively scheduled for August 19, 1993 in Birmingham, Alabama.

Some of these depositions may not bear on the issue of causation and may be unnecessary if the requested scheduling order is granted.

14.

The parties' desire to reschedule Dr. Robertson's deposition due to the difficult travel arrangements necessary to

travel from Lexington, Kentucky on the evening of July 13 (following Dr. Robertson's deposition of July 13) to Binghamton, New York for Dr. Schecter's deposition on July 14. While it is logistically possible (there is one available night flight, assuming good weather), it would make more sense to extend the discovery deadline beyond August 3 so that Dr. Robertson's deposition can be conveniently rescheduled.

15.

The depositions for the following additional witnesses will need to be scheduled on the issue of causation:

a. The deposition of Dr. Teitelbaum from Denver, Colorado will need to be taken;

b. The deposition of Dr. Frank from Lexington, Kentucky will need to be taken;

c. The deposition of Dr. Cole from Birmingham, Alabama will need to be taken;

d. The deposition of Dr. Waddell from Louisville, Kentucky will need to be taken.

16.

Counsel for Plaintiffs and General Electric both have family vacations scheduled for the first two weeks of August, 1993.

CONCLUSION:

For the foregoing reasons, the parties collectively request that this Court enter a Scheduling Order requiring that all parties identify any and all expert witnesses on the issue of causation of Robert Joiner's illness on or before September 1, 1993, and that the depositions of all expert witnesses on the issue of causation be scheduled and taken on or before November 1, 1993. The parties further collectively request that a deadline of Wednesday, December

1, 1993 be set for the filing of any motions in limine or for summary judgment on issues relating to causation of Robert K. Joiner's illness. Until further order of this Court, discovery on issues unrelated to causation shall be stayed pending a ruling on any motion(s) for summary judgment. However, to prevent duplicate depositions and unnecessary expense, the parties may inquire into all areas about which a witness has knowledge. If an issue of fact is found to exist by this Court with respect to causation, the parties will then be allowed a reasonable discovery period for other issues including, but not limited to, negligence, strict liability, and damages.

Respectfully submitted this 9th day of July, 1993.

Counsel for General Electric

/s/ Anthony L. Cochran
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Georgia Bar No. 172425

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[Filed Jul. 12, 1993]

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

ORDER

The parties having consented,

IT IS HEREBY ORDERED that all parties shall identify any and all expert witnesses on the issue of causation of Robert K. Joiner's illness on or before September 1, 1993, and that the depositions of all expert witnesses on the issue of causation shall be scheduled and taken on or before November 1, 1993. It is hereby further ordered that on or before Wednesday, December 1, 1993, all motion(s) in limine or for summary judgment on issues relating to causation of Robert K. Joiner's illness shall be filed. Until further order of this Court, discovery on issues unrelated to causation shall be stayed pending a ruling on any motions in limine or for summary judgment. However, to prevent duplicate depositions and unnecessary expense, the parties may inquire into all areas about which a witness has knowledge. If an issue of fact is found to exist by this Court with respect to causation, the parties will then be allowed a reasonable period for discovery of other issues including, but not limited to, negligence, strict liability, damages, and the defendants' denial of liability for plaintiffs' injuries.

SO ORDERED, this 13 day of July, 1993.

/s/ Orinda D. Evans
ORINDA D. EVANS
Judge
United States District Court
for the Northern District of
Georgia

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

FIRST AMENDED COMPLAINT

NOW COME Plaintiffs, in compliance with this Court's Order dated August 4, 1993, and file this First Amended Complaint against Defendants as follows:

1.

Defendant, General Electric Company, a New York corporation, ("GE") maintains its registered agent in Fulton County, Georgia, committed a tortuous act in Georgia, and is subject to the jurisdiction of the courts of this state, venue in this Court is proper, and it may be served with Summons and Complaint as allowed by law.

2.

Defendant, Westinghouse Electric Corporation, a Pennsylvania corporation ("Westinghouse") maintains its registered agent in Fulton County, Georgia, committed a tortuous act in Georgia, and is subject to the jurisdiction of the courts of this state, venue in this Court is proper, and it may be served with Summons and Complaint as allowed by law.

3.

Defendant, Monsanto Company, a Delaware corporation, ("Monsanto") maintains its registered agent in Fulton County, Georgia, committed a tortuous act in Georgia, and is subject to the jurisdiction of the courts of this

state, venue in this Court is proper, and it may be served with Summons and Complaint as allowed by law.

4.

Defendant Monsanto manufactured Polychlorinated Biphenyls ("PCB") to be used in the manufacturing, testing and as a cooling fluid in electrical transformers manufactured by Defendants GE and Westinghouse.

5.

Defendants GE and Westinghouse manufactured and sold as new products electrical transformers containing PCB fluid manufactured by Defendant Monsanto.

6.

At the time of the manufacturing of these transformers with PCB fluid used in the manufacturing, testing and ultimate product, all Defendants were aware that PCBs were unreasonably dangerous and likely to cause injury and death to human beings who were exposed to the PCB fluids, including PCB residues in mineral oil fluids, during service and use of the transformer products.

7.

Plaintiff Robert K. Joiner was an ultimate, foreseeable, intended user and service of the transformer products manufactured by Defendants GE and Westinghouse which contained PCB fluids, and PCB contamination, manufactured by Defendant Monsanto.

8.

Throughout the course of his use of the transformers in his capacity as a repairman, Plaintiff Robert K. Joiner was caused to be exposed to PCB, was caused to be exposed to PCB fumes, and was caused to inhale PCB con-

taminated fluids, mists, liquids, and steams and he was also caused to absorb PCB through contact with his skin.

9.

As a result of Plaintiff Robert K. Joiner's exposure to PCBs, he contracted terminal lung cancer.

COUNT ONE
(STRICT LIABILITY AGAINST DEFENDANTS GE AND WESTINGHOUSE)

10.

Plaintiffs repeat, reallege, and incorporate by reference, the allegations of paragraphs 1 through 9 as if repeated herein as paragraph 10.

11.

Defendants put an unreasonably dangerous and defective product, the PCB contaminated electrical transformers, into the stream of commerce. The defect was the proximate cause of a serious bodily injury sustained by Plaintiff Robert K. Joiner. As a result, Defendants are strictly liable to Plaintiff.

12.

As a direct and proximate result of Defendants' acts, Plaintiff Robert K. Joiner was injured and suffered damages including permanent physical disfigurement, permanent physical disability, past pain and suffering, future pain and suffering, past medical expenses and lost wages, and future medical expenses and lost wages, all entitling him to an award of damages in his favor and against Defendants, and each of them, jointly and severally, in an amount in excess of Ten Million Dollars ($10,000,000.00).

COUNT TWO
(NEGLIGENCE AGAINST DEFENDANTS GE AND WESTINGHOUSE)

13.

Plaintiffs repeat, reallege, and incorporate by reference, the allegations of paragraphs 1 through 12 as if repeated herein as paragraph 13.

14.

Defendants GE and Westinghouse negligently manufactured and distributed the electrical transformers in that: (i) the electrical transformers were sold in a condition which allowed it to be contaminated with PCBs and cause serious injury in expected use; (ii) the electrical transformers were defective in that they were manufactured and sold with PCB contamination which was likely to cause injury in the use for which they were intended; and (iii) the electrical transformers were sold without adequate warnings and instructions with respect to the known and unknown dangers of PCBs contained within them. This negligence was the proximate cause of a serious bodily injury sustained by Plaintiff.

15.

As a direct and proximate result of Defendant GE's and Westinghouse's negligence, Plaintiff was injured and has suffered damages including permanent physical disfigurement, permanent physical disability, past pain and suffering, future pain and suffering, past medical expenses and lost wages, and future medical expenses and lost wages, all entitling him tc an award of damages in his favor and against Defendants, and each of them, jointly and severally, in an amount in excess of Ten Million Dollars ($10,000,000.00).

COUNT THREE
(FRAUD AGAINST DEFENDANTS GE AND WESTINGHOUSE)

16.

Plaintiffs repeat, reallege, and incorporate by reference, the allegations of paragraphs 1 through 15 as if repeated herein as paragraph 16.

17.

Defendants GE and Westinghouse represented to the buying public and those who serviced their electrical transformer products, including Plaintiff Robert K. Joiner, that the electrical transformer products were free from PCBs and were safe in regular use and servicing.

18.

Defendants GE and Westinghouse intended for the buying public and those who serviced their electrical transformer products, including Plaintiff Robert K. Joiner, to rely on their representations that the electrical transformer products were free from PCB and were safe in regular use and servicing.

19.

The buying public and those who serviced their electrical transformer products, including and particularly Plaintiff Robert K. Joiner, reasonably relied on the representations of Defendants GE and Westinghouse that the electrical transformer products were free from PCBs and were safe in regular use and servicing and as a result Plaintiff Robert K Joiner took no precautions to protect himself when handling and servicing the electrical transformer products.

20.

As a direct and proximate result of the justifiable reliance on Defendant GE's and Westinghouse's fraudulent misrepresentations, Plaintiff Robert K. Joiner was exposed

to PCBs and was caused to contract terminal lung cancer and was otherwise injured and has suffered damages including permanent physical disfigurement, permanent physical disability, past pain and suffering, future pain and suffering, past medical expenses and lost wages, and future medical expenses and lost wages, all entitling him to an award of damages in his favor and against Defendants, and each of them, jointly and severally, in an amount in excess of Ten Million Dollars ($10,000,000.00).

COUNT FOUR
(STRICT LIABILITY AGAINST DEFENDANT MONSANTO)

21.

Plaintiffs repeat, reallege, and incorporate by reference, the allegations of paragraphs 1 through 20 as if repeated herein as paragraph 21.

22.

Defendant Monsanto put an unreasonably dangerous and defective product, the PCB fluids, into the stream of commerce. The defect was the proximate cause of a serious bodily injury sustained by Plaintiff Robert K. Joiner. As a result, Defendants are strictly liable to Plaintiff.

23.

As a direct and proximate result of Defendant Monsanto's acts, Plaintiff Robert K. Joiner was injured and suffered damages including permanent physical disfigurement, permanent physical disability, past pain and suffering, future pain and suffering, past medical expenses and lost wages, and future medical expenses and lost wages, all entitling him to an award of damages in his favor and against Defendants, and each of them, jointly and severally, in an amount in excess of Ten Million Dollars ($10,000,000.00).

COUNT FIVE
(NEGLIGENCE AGAINST DEFENDANT MONSANTO)

24.

Plaintiffs repeat, reallege, and incorporate by reference, the allegations of paragraph 1 through 23 as if repeated herein as paragraph 24.

25.

Defendant Monsanto negligently manufactured and distributed the PCB fluid in that: (i) the PCB fluid was unreasonably dangerous and known to be likely to cause serious injury in expected use; (ii) the PCB fluid was sold without adequate warnings and instructions with respect to the known and unknown dangers of PCBs. This negligence was the proximate cause of a serious bodily injury sustained by Plaintiff.

26.

As a direct and proximate result of Defendant Monsanto's negligence, Plaintiff was injured and has suffered damages including permanent physical disfigurement, permanent physical disability, past pain and suffering, future pain and suffering, past medical expenses and lost wages, and future medical expenses and lost wages, all entitling him to an award of damages in his favor and against Defendants, and each of them, jointly and severally, in an amount in excess of Ten Million Dollars ($10,000,000.00).

COUNT SIX
(LOSS OF CONSORTIUM AGAINST ALL DEFENDANTS)

27.

Plaintiffs repeat, reallege, and incorporate by reference, the allegations of paragraphs 1 through 26 as if repeated herein as paragraph 27.

28.

At all times relevant to this action, Plaintiff Karen P. Joiner has been the wife of Plaintiff Robert K. Joiner.

29.

As a direct and proximate result of the wrongful conduct of Defendants, and each of them, Plaintiff Robert K. Joiner suffered severe and permanent bodily injuries including serious and permanent physical and emotional injury and disability, substantial and continuing pain, suffering, and discomfort, and lost wages and medical expenses, both past and future. As a result of these injuries to her husband, Plaintiff Karen P. Joiner has lost the domestic and conjugal services previously provided to her by her husband and has been deprived of her right to consortium.

30.

As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Karen P. Joiner is entitled to an award of general damages for her loss of consortium in an amount to be determined by a jury of her peers in an amount in excess of Ten Million Dollars ($10,000,000.00) against each of them, jointly and severally.

COUNT SEVEN
(BATTERY AGAINST ALL DEFENDANTS)

31.

Plaintiffs repeat, reallege, and incorporate by reference, the allegations of paragraphs 1 through 30 as if repeated herein as paragraph 31.

32.

Defendants caused a harmful product to contact Plaintiff Robert K. Joiner which contact was not necessary, was not privileged, and constituted a harmful or offensive contact, consisting of a battery to Plaintiff's person in wanton disregard of Plaintiff's rights.

33.

As a direct and proximate result of Defendants' battery of Plaintiff's person, Plaintiff Robert K. Joiner Plaintiff was injured and has suffered damages including permanent physical disfigurement, permanent physical disabiilty, past pain and suffering, future pain and suffering, past medical expenses and lost wages, and future medical expenses and lost wages, all entitling him to an award of damages in his favor and against Defendants, and each of them, jointly and severally, in an amount in excess of Ten Million Dollars ($10,000,000.00).

COUNT EIGHT
(PUNITIVE DAMAGES AGAINST ALL DEFENDANTS)

34.

Plaintiffs repeat, reallege, and incorporate by reference, the allegations of paragraphs 1 through 33 as if repeated herein as paragraph 34.

35.

Defendants' conduct in defrauding Plaintiff is intentional, in bad faith, and in wanton disregard of Plaintiff's rights. Defendants' conduct in distributing and selling defective and dangerous products which Defendants knew were likely to cause bodily injury was willful, wanton, and in callous disregard for human health and safety.

36.

As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs are entitled to judgment against Defendants, and each of them, jointly and severally, for exemplary damages to deter each of them from similar conduct in the future and to punish them for their wrongful acts in an amount to be determined by the enlightened conscience of the finder of fact in an amount in excess of Twenty Million Dollars ($20,000,000.00).

WHEREFORE, Plaintiffs pray that summons issue, that Defendants be served and made to appear and answer, that a JURY TRIAL be held, and that they be awarded judgment in their favor and against the Defendants, jointly and severally, as follows:

(a) Under Count One, that Plaintiff Robert K. Joiner be awarded his special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00);

(b) Under Count Two, that Plaintiff Robert K. Joiner be awarded his special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00);

(c) Under Count Three, that Plaintiff Robert K. Joiner be awarded his special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00);

(d) Under Count Four, that Plaintiff Robert K. Joiner be awarded his special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00);

(e) Under Count Five, that Plaintiff Robert K. Joiner be awarded his special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00);

(f) Under Count Six, that Plaintiff Karen P. Joiner be awarded her special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00);

(g) Under Count Seven, that Plaintiff Robert K. Joiner be awarded his special damages as are proved at trial plus an appropriate amount as general damages in an amount in excess of Ten Million Dollars ($10,000,000.00);

(h) Under Count Eight, that Plaintiffs be awarded punitive damages in an amount in excess of Twenty Million Dollars ($20,000,000.00);

(i) That the cost of this action be levied against Defendants; and,

(j) That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Respectfully Submitted,
BURGE & WETTERMARK

By: /s/ Michael J. Warshauer
MICHAEL J. WARSHAUER
Georgia Bar Number 018720

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DICTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

**ANSWER OF THE DEFENDANT,
MONSANTO COMPANY,
TO FIRST AMENDED COMPLAINT**

COMES NOW, MONSANTO COMPANY (hereinafter "Monsanto"), Defendant in the above-styled cause, and for Answer to Plaintiffs' First Amended Complaint, shows the following:

FIRST DEFENSE:

In answer to the numbered paragraphs of Plaintiffs' First Amended Complaint, Defendant MONSANTO says:

1.

This Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph One (1) of Plaintiffs' First Amended Complaint.

2.

This Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph Two (2) of Plaintiffs' First Amended Complaint.

3.

With respect to the allegations contained in Paragraph Three (3) of Plaintiffs' First Amended Complaint, this Defendant denies that MONSANTO has committed a tortious act in Georgia but admits the remaining allegations contained in Paragraph Three (3).

4.

MONSANTO admits that from time to time it manufactured polychlorinated biphenlys which were sold in bulk to General Electric Company, and Westinghouse Electric Corporation, among others, for use in fire resistant dielectric fluid in electrical transformers. Except as herein admitted, Monsanto denies the remaining allegations of Paragraph Four (4) of Plaintiffs' First Amended Complaint.

5.

The allegations contained in Paragraph Five (5) of Plaintiffs' First Amended Complaint are admitted.

6.

The allegations contained in Paragraph Six (6) of Plaintiffs' First Amended Complaint are denied.

7.

The allegations contained in Paragraph Seven (7) of Plaintiffs' First Amended Complaint are denied.

8.

The allegations contained in Paragraph Eight (8) of Plaintiffs' First Amended Complaint are denied.

9.

The allegations contained in Paragraph Nine (9) of Plaintiffs' First Amended Complaint are denied.

COUNT ONE
(STRICT LIABILITY AGAINST DEFENDANTS
G.E. AND WESTINGHOUSE)

10.

In response to the allegations contained in Paragraph Ten (10) of COUNT ONE of Plaintiffs' First Amended

Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answer to the allegations contained in Paragraphs 1 through 9.

11.

The allegations contained in Paragraph Eleven (11) of COUNT ONE of Plaintiffs' First Amended Complaint are not directed to this Defendant, and thus require no answer of the Defendant MONSANTO.

12.

The allegations contained in Paragraph Twelve (12) of COUNT ONE of Plaintiffs' First Amended Complaint are not directed to this Defendant, and thus require no answer of the Defendant MONSANTO.

COUNT TWO
(NEGLIGENCE AGAINST DEFENDANTS G.E. AND WESTINGHOUSE)

13.

In response to the allegations contained in Paragraph Thirteen (13) of COUNT TWO of Plaintiffs' First Amended Complaint, Defendant MONSANTO, realleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 12.

14.

The allegations contained in Paragraph Fourteen (14) of COUNT TWO of Plaintiffs' First Amended Complaint are not directed to this Defendant, and thus require no answer of the Defendant MONSANTO.

15.

The allegations contained in Paragraph Fifteen (15) of COUNT TWO of Plaintiffs' First Amended Complaint

are not directed to this Defendant, and thus require no answer of the Defendant MONSANTO.

COUNT THREE
(FRAUD AGAINST DEFENDANTS G.E. AND WESTINGHOUSE)

16.

In response to the allegations contained in Paragraph Sixteen (16) of COUNT THREE of Plaintiffs' First Amended Complaint, Defendant MONSANTO alleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 15.

17.

The allegations contained in Paragraph Seventeen (17) of COUNT THREE of Plaintiffs' First Amended Complaint are not directed to this Defendant, and thus require no answer of the Defendant MONSANTO.

18.

The allegations contained in Paragraph Eighteen (18) of COUNT THREE of Plaintiffs' First Amended Complaint are not directed to this Defendant, and thus require no answer of the Defendant MONSANTO.

19.

The allegations contained in Paragraph Nineteen (19) of COUNT THREE of Plaintiffs' First Amended Complaint are not directed to this Defendant, and thus require no answer of the Defendant MONSANTO.

20.

The allegations contained in Paragraph Twenty (20) of COUNT THREE of Plaintiffs' First Amended Complaint are not directed to this Defendant, and thus require no answer of the Defendant MONSANTO.

COUNT FOUR

21.

In response to the allegations contained in Paragraph Twenty-One (21) of COUNT FOUR of Plaintiffs First Amended Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 20.

22.

The allegations contained in Paragraph Twenty-Two (22) of COUNT FOUR of Plaintiffs' First Amended Complaint are denied.

23.

The allegations contained in Paragraph Twenty-Three (23) of COUNT FOUR of Plaintiffs' First Amended Complaint are denied.

COUNT FIVE

24.

In response to the allegations contained in Paragraph Twenty-Four (24) of COUNT FIVE of Plaintiffs' First Amended Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 23.

25.

The allegations contained in Paragraph Twenty-Five (25) of COUNT FIVE of Plaintiffs' First Amended Complaint are denied.

26.

The allegations contained in Paragraph Twenty-Six (26) of COUNT FIVE of Plaintiffs' First Amended Complaint are denied.

COUNT SIX

27.

In response to the allegations contained in Paragraph Twenty-Seven (27) of COUNT SIX of Plaintiffs' First Amended Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 26.

28.

This Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph Twenty-Eight (28) of COUNT SIX of Plaintiffs' First Amended Complaint and therefore the allegations are denied.

29.

The allegations contained in Paragraph Twenty-Nine (29) of COUNT SIX of Plaintiffs' First Amended Complaint are denied.

30.

The allegations contained in Paragraph Thirty (30) of COUNT SIX of Plaintiffs' First Amended Complaint are denied.

COUNT SEVEN

31.

In response to the allegations contained in Paragraph Thirty-One (31) of COUNT SEVEN of Plaintiffs' First Amended Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 30.

32.

The allegations contained in Paragraph Thirty-Two (32) of COUNT SEVEN of Plaintiffs' First Amended Complaint are denied.

33.

The allegations contained in Paragraph Thirty-Three (33) of COUNT SEVEN of Plaintiffs' First Amended Complaint are denied.

COUNT EIGHT

34.

In response to the allegations contained in Paragraph Thirty-Four (34) of COUNT EIGHT of Plaintiffs' First Amended Complaint, Defendant MONSANTO realleges, adopts and incorporates herein its answers to the allegations contained in Paragraphs 1 through 33.

35.

The allegations contained in Paragraph Thirty-Five (35) of COUNT EIGHT of Plaintiffs' First Amended Complaint are denied.

36.

The allegations contained in Paragraph Thirty-Six (36) of COUNT EIGHT of Plaintiffs' First Amended Complaint are denied.

SECOND DEFENSE

Any allegation in Plaintiffs' First Amended Complaint not specifically responded to in this Answer is herewith denied.

PREAMBLE TO AFFIRMATIVE DEFENSES

The Defendant MONSANTO reserves the right to rely upon the following defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or by evidence at trial:

THIRD DEFENSE

Plaintiffs' Complaint fails to state a claim against Defendant MONSANTO upon which relief can be granted.

FOURTH DEFENSE

No act or omission on the part of the Defendant MONSANTO either proximately caused or contributed to any injury alleged to have been sustained by Plaintiffs.

FIFTH DEFENSE

Upon information and belief, this Defendant says that Plaintiff ROBERT K. JOINER assumed the risk of injury, if any he sustained, himself and therefore is not entitled to recover of this Defendant.

SIXTH DEFENSE

Defendant MONSANTO says that, even if it was negligent in the manner set out and charged in the First Amended Complaint, which alleged negligence is expressly denied, the negligence of Plaintiff ROBERT K. JOINER was equal to or greater than any negligence charged against this Defendant in such First Amended Complaint and the consequences of such negligence, if any in fact existed, could have been avoided had ROBERT K. JOINER been in the exercise of ordinary care.

SEVENTH DEFENSE

Upon information and belief, Plaintiff ROBERT K. JOINER has failed, in whole or in part, to mitigate and/or avoid any alleged injury purportedly sustained by Plaintiffs.

EIGHTH DEFENSE

Plaintiffs' claims for punitive damages are in violation of and barred by the due process clause of the 1983 Georgia Constitution, Article 1, Section 1, Paragraph 1, and by the Fifth and Fourteenth Amendments to the United States Constitution.

NINTH DEFENSE

Plaintiffs' claims for punitive damages are in violation of and barred by the equal protection clause of the 1983 Georgia Constitution, Article 1, Section 1, Paragraph 2, and by the Fourteenth Amendment to the United States Constitution.

TENTH DEFENSE

Upon information and belief, if Plaintiff ROBERT K. JOINER was exposed to polychlorinated biphenyls "PCBs") alleged to have been manufactured by MONSANTO and if Plaintiff ROBERT K. JOINER incurred any injury resulting therefrom, all of which is expressly denied, Plaintiff ROBERT K. JOINER's injury would not have occurred but for the fact that the "PCBs" were materially changed or altered by Plaintiff ROBERT K. JOINER or others, whether or not such others are parties to this action, and such material change or alteration was not made in accordance with the instructions of MONSANTO, was not made with the consent of MONSANTO or was not the result of conduct that reasonably should have been anticipated by MONSANTO, and therefore Plaintiff ROBERT K. JOINER's claim is barred.

ELEVENTH DEFENSE

Upon information and belief, if Plaintiff ROBERT K. JOINER sustained any injury or damage as alleged in the Complaint, which is denied, such injury was due to, caused by or contributed to, in whole or in part, to the negligence or carelessness of other parties over whom MONSANTO had no control and for whose conduct MONSANTO is not responsible. Such negligence of other parties was the sole proximate cause of, or an intervening, superseding, or insulating cause of the Plaintiffs' alleged damages.

TWELFTH DEFENSE

Upon information and belief, it is alleged that the Plaintiff ROBERT K. JOINER's employer at the time of the alleged exposure to "PCBs" was negligent in that the employer failed properly and safely to equip the Plaintiff ROBERT K. JOINER with the necessary protection; that the employer provided the orders and directions under which the Plaintiff ROBERT K. JOINER worked with or in the area of "PCBs" (if he did so); that the employer allowed "PCBs" to be used by the Plaintiff ROBERT K. JOINER and others in a manner so as to create a condition of danger for the Plaintiff ROBERT K. JOINER: that although the employer knew or should have known in the exercise of ordinary care of the general requirements of the handling of "PCBs", the employer nevertheless failed to relate all such information to the Plaintiff ROBERT K. JOINER; that the employer failed to provide a safe place for the Plaintiff ROBERT K. JOINER to work; that the employer failed to provide suitable training and education for its employees, including the Plaintiff ROBERT K. JOINER; that the employer failed to require the Plaintiff ROBERT K. JOINER and others to keep the premises and their persons clean and in a normal state of good housekeeping and cleanliness. If the Plaintiff ROBERT K. JOINER sustained any injury or damage as set forth in the Complaint, which is denied, the same was directly and proximately caused by the foregoing negligence of the Plaintiff ROBERT K. JOINER's employer and such negligence was the sole proximate cause of or an intervening, superseding or insulating cause of the Plaintiff ROBERT K. JOINER's injury and damage, if any.

THIRTEENTH DEFENSE

Any purchaser or user who purchased or used "PCBs" alleged to have been manufactured by MONSANTO, as the developers and manufacturers of the final product to

which the Plaintiff ROBERT K. JOINER was allegedly exposed, were sophisticated and knowledgeable users of "PCBs" and were in a far better position to instruct or warn Plaintiff ROBERT K. JOINER and, if any such instruction or warning was legally required, which is denied, their failure to instruct or warn the Plaintiff ROBERT K. JOINER was an intervening, superseding or insulating proximate cause of Plaintiff ROBERT K. JOINER's alleged injuries.

FOURTEENTH DEFENSE

If Plaintiff ROBERT K. JOINER was exposed to any "PCBs" alleged to have been manufactured by MONSANTO and if Plaintiff ROBERT K. JOINER incurred any injury resulting therefrom, all of which is expressly denied, Plaintiff ROBERT K. JOINER's claim is barred by the applicable statutes of limitations and/or repose.

WHEREFORE, the Defendant MONSANTO respectfully demands that judgment be rendered in its favor.

FREEMAN & HAWKINS

/s/ Joe C. Freeman, Jr.
JOE C. FREEMAN, JR.
GA State Bar No. 275700

/s/ Joanne Beauvoir Brown
JOANNE BEAUVOIR BROWN
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Monsanto Company

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

ANSWER OF DEFENDANT WESTINGHOUSE ELECTRIC CORPORATION TO FIRST AMENDED COMPLAINT

COMES NOW defendant Westinghouse Electric Corporation and hereby raises its defenses and answers plaintiffs' first amended complaint (hereinafter "plaintiffs' complaint") as follows:

FIRST DEFENSE

Plaintiffs' complaint fails to state a claim upon which relief may be granted.

SECOND DEFENSE

Plaintiffs' complaint is barred by the statute of limitations.

THIRD DEFENSE

Plaintiffs' complaint is barred by the statute of repose.

FOURTH DEFENSE

Plaintiffs are barred from any recovery under the doctrine of assumption of risk.

FIFTH DEFENSE

Plaintiffs are barred from any recovery in whole or in part by the contributory negligence or comparative fault of plaintiffs.

SIXTH DEFENSE

The allegations of fraud set forth in count three, paragraphs 16-20, of the plaintiffs' complaint, are not stated with the requisite particularity.

SEVENTH DEFENSE

The plaintiffs have failed to specifically state items of special damages.

EIGHTH DEFENSE

Having raised its affirmative defenses and without waiving said defenses, defendant Westinghouse responds to each and every paragraph of the plaintiffs' complaint as follows:

1.

Defendant Westinghouse is without sufficient knowledge or information upon which to form a belief as to the truth or accuracy of the allegations contained in paragraph 1 of the plaintiffs' complaint.

2.

Defendant Westinghouse admits that it is a Pennsylvania corporation, that it maintains a registered agent in Fulton County, Georgia, and that it is subject to the jurisdiction and venue of this Court. Defendant Westinghouse denies that it commited a tortious act in Georgia as alleged in plaintiffs' complaint and denies all remaining allegations of paragraph 2 of the plaintiffs' complaint.

3.

Defendant Westinghouse is without sufficient knowledge or information upon which to form a belief as to the truth or accuracy of the allegations contained in paragraph 3 of the plaintiffs' complaint.

4.

Defendant Westinghouse admits that it purchased from Monsanto Company quantities of polychlorinated biphenyls for use in certain electrical transformers it manufactured. Defendent Westinghouse denies the remaining allegations of paragraph 4 of plaintiffs' complaint.

5.

Defendant Westinghouse admits that it was a manufacturer of electrical transformers which contained polychlorinated biphenyls and that some of these transformers contained polychlorinated biphenyls purchased from Monsanto Company. Defendant Westinghouse is without sufficient knowledge or information upon which to form a belief as to the truth or accuracy of the plaintiffs' allegations concerning General Electric Company.

6.

Defendant Westinghouse denies the allegations contained in paragraph 6 of the plaintiffs' complaint.

7.

Defendant Westinghouse denies the allegations contained in paragraph 7 of the plaintiffs' complaint.

8.

Defendant Westinghouse denies the allegations contained in paragraph 8 of the plaintiffs' complaint.

9.

Defendant Westinghouse denies the allegations contained in paragraph 9 of the plaintiffs' complaint.

10.

In response to paragraph 10 of the plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 9 of the plaintiffs' complaint with the same force and effect as if they had been restated herein.

11.

Defendant Westinghouse denies the allegations contained in paragraph 11 of the plaintiffs' complaint.

12.

Defendant Westinghouse denies the allegations contained in paragraph 12 of the plaintiffs' complaint.

13.

In response to paragraph 13 of plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 12 of the plaintiffs' complaint with the same force and effect as if they had been restated herein.

14.

Defendant Westinghouse denies the allegations contained in paragraph 14 of the plaintiffs' complaint.

15.

Defendant Westinghouse denies the allegations contained in paragraph 15 of the plaintiffs' complaint.

16.

In response to paragraph 16 of plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 15 of the plaintiffs' complaint with the same force and effect as if they had been restated herein.

17.

Defendant Westinghouse denies the allegations contained in paragraph 17 of the plaintiffs' complaint.

18.

Defendant Westinghouse denies the allegations contained in pargraph 18 of the plaintiffs' complaint.

19.

Defendant Westinghouse denies the allegations contained in paragraph 19 of the plaintiffs' complaint.

20.

Defendant Westinghouse denies the allegations contained in paragraph 20 of the plaintiffs' complaint.

21.

In response to paragraph 21 of the plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 20 of the plaintiffs' complaint with the same force and effect as if they had been restated herein.

22.

Defendant Westinghouse denies the allegations contained in paragraph 22 of the plaintiffs' complaint.

23.

Defendant Westinghouse denies the allegations contained in paragraph 23 of the plaintiffs' complaint.

24.

In response to paragraph 24 of plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 23 of the plaintiffs' complaint with the same force and effect as if they had been restated herein.

25.

Defendant Westinghouse denies the allegations contained in paragraph 25 of the plaintiffs' complaint.

26.

Defendant Westinghouse denies the allegations contained in paragraph 26 of the plaintiffs' complaint.

27.

In response to paragraph 27 of plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 26 of the plaintiffs' complaint with the same force and effect as if they had been restated herein.

28.

Defendant Westinghouse is without sufficient knowledge or information upon which to form a belief as to the truth or accuracy of the allegations contained in paragraph 28 of the plaintiffs' complaint.

29.

Defendant Westinghouse denies the allegations contained in paragraph 29 of the plaintiffs' complaint.

30.

Defendant Westinghouse denies the allegations contained in paragraph 30 of the plaintiffs' complaint.

31.

In response to paragraph 31 of plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 30 of the plaintiffs' complaint with the same force and effect as if they had been restated herein.

32.

Defendant Westinghouse denies the allegations contained in paragraph 32 of the plaintiffs' complaint.

33.

Defendant Westinghouse denies the allegations contained in paragraph 33 of the plaintiffs' complaint.

34.

In response to paragraph 34 of plaintiffs' complaint, defendant Westinghouse realleges and incorporates herein its responses to paragraphs 1 through 33 of the plaintiffs' complaint with the same force and effect as if they had been restated herein.

35.

Defendant Westinghouse denies the allegations contained in paragraph 35 of the plaintiffs' complaint.

36.

Defendant Westinghouse denies the allegations contained in paragraph 36 of the plaintiffs' complaint.

WHEREFORE, having asserted its affirmative defenses and having answered plaintiffs' first amended complaint, defendant Westinghouse demands judgment that the plaintiffs' first amended complaint be dismissed with all costs cast against plaintiffs.

This the 2nd day of September, 1993.

/s/ David H. Flint
DAVID H. FLINT
Georgia Bar No. 264600
ALEX J. SIMMONS, JR.
Georgia Bar No. 646990
Attorneys for defendant
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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

ANSWER OF GENERAL ELECTRIC COMPANY TO FIRST AMENDED COMPLAINT

The defendant, General Electric Company (hereinafter "General Electric") hereby answers the First Amended Complaint as follows:

General Electric incorporates by reference and adopts its answer to the original complaint, specifically adopting and incorporating by reference in their entirety the First through the Fourteenth Defenses.

Additionally, General Electric answers the new Count Seven contained in the Amended Complaint as follows:

31.

Answering paragraph 31 of the First Amended Complaint, General Electric incorporates by reference its answers to paragraphs 1 through 30 of the First Amended Complaint as if restated verbatim.

32.

General Electric denies the allegations in paragraph 32 of the First Amended Complaint.

33.

General Electric denies the allegations in paragraph 33 of the First Amended Complaint.

As Count Seven in the original Complaint has now been characterized as Count Eight in the First Amended Complaint, General Electric incorporates by reference and adopts its answer to Count Seven from the original Complaint as though it were answering Count Eight in the First Amended Complaint.

WHEREFORE, having fully answered the First Amended Complaint, General Electric demands judgment in its favor as follows:

1) dismissing the First Amended Complaint with prejudice;

2) awarding all costs of litigation to General Electric; and

3) awarding all such other relief to General Electric as this Court deems proper.

This 3rd day of September, 1993.

Respectfully submitted,

/s/ Anthony L. Cochran
ANTHONY L. COCHRAN
Georgia Bar No. 172425

CHILIVIS & GRINDLER
3127 Maple Drive, N.E.
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[Filed Dec. 8, 1993]

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

DEFENDANTS' JOINT MOTION FOR SUMMARY JUDGMENT

The defendants, General Electric Company, Westinghouse Electric Corporation, and Monsanto Company, hereby jointly move for summary judgment in accordance with Rule 56 of the Federal Rules of Civil Procedure and Local Rule 220 on the ground that there is no genuine issue as to any material fact and that defendants are entitled to judgment as a matter of law. This motion is accompanied by a separate joint memorandum of law, as well as a separate and concise statement of material facts, all of which are filed contemporaneously with this joint motion.

Additionally, in accordance with Local Rule 220-5 (b)(3), the defendants are relying upon the following materials in support of their joint motion for summary judgment:

1. The deposition of Dr. Arnold Schecter, an expert witness retained by the plaintiffs;

2. Dr. Daniel Teitelbaum, a second expert witness retained by the plaintiffs;

3. Dr. Larry Robertson, a third expert witness retained by the plaintiffs;

4. The Declaration of Mary [*sic*—Mark] Homyk, an employee at The City of Thomasville Water & Light Department, Mr. Robert K. Joiner's employer;

5. The deposition transcript of the plaintiff, Robert K. Joiner.

6. The deposition transcript of Dr. Philip Cole, an epidemiologist retained by the defendants;

7. The deposition transcript of Dr. William Waddell, a toxicologist retained by the defendants;

8. The deposition transcript of Dr. William Bailey, a pulmonary expert retained by the defendants;

9. The deposition transcript of Dr. Thomas O. Rouse, a GE employee;

10. The deposition transcript of Dr. John E. Brown, Jr., a GE employee;

11. The deposition transcript of Dr. Stephen B. Hamilton, Jr., a GE employee;

12. The deposition transcript of Dr. George Frame, a GE employee;

13. The Declaration of Anthony L. Cochran, counsel for General Electric Company, concerning documents produced by the plaintiffs in this litigation;

14. The Declaration of Susan Van Vlack, a paralegal working with counsel for GE, concerning documents produced by the plaintiffs and The City of Thomasville Water & Light Department;

WHEREFORE General Electric Company, Westinghouse Electric Corporation, and Monsanto Company request that this motion be granted and that judgment be entered in their favor, dismissing with prejudice plaintiffs' complaint, with costs upon plaintiffs, and that defendants have such other and further relief as is just and proper.

This 8th day of December, 1993.

/s/ Anthony L. Cochran
(by ALC with
express permission)
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Attorney for Defendant
General Electric Company

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/s/ Joe C. Freeman
(by ALC with
express permission)
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[1]
IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

A Deposition held at the Bache Building, Binghamton, New York, on the 14th day of July, 1993, commencing at 9:15 AM.

* * * *

ARNOLD J. SCHECTER, MD, having been called as a witness, being duly sworn, testified as follows:

* * * *

[20] Q. You mentioned a moment ago you reviewed [21] the adipose tissue test results. Did you at one point request that additional either adipose tissue or blood serum tests be run on Mr. Joiner?

A. I do not recall requesting that.

Q. Are you saying that you could have and you don't recall or you never did request them?

A. I just don't recall requesting them.

* * * *

[24] Q. In your standard practice, isn't it routine and customary for you to have blood tests run so that you can get a congener—congener specific level determined for dioxins, furans and PCBs?

A. No, it is not.

Q. To your knowledge, has another blood test for Mr. Joiner to determine dioxin levels actually [25] been done?

A. Not that I know of.

* * * *

[26] Q. Let me ask my question again, then. Do you have an opinion to a reasonable degree of medical certainty that, in fact, the chemotherapy and radiation

therapy that Robert Joiner underwent affected the level of PCBs, furans and dioxins in his adipose tissue?

[27] A. I would be surprised if there were not alterations, but I have no empirical evidence upon which to come to a conclusion.

* * *

[31] Q. Let's return to the results from Triangle Laboratories. You have seen those, have you not?

A. Yes.

Q. You say you saw those yesterday and you saw them also back when you were in Atlanta?

A. Yes, sir, that's correct.

Q. Do you recall what the total body burden was for Mr. Joiner reflected on those tests?

A. Yes, I do.

Q. What is your recollection?

A. For the most part, the dioxin and dibenzofuran levels were listed as nondetect or nondetectable. And the summation of the PCB congeners by the method employed by Triangle [32] Laboratory was roughly four-tenths of a part per million.

Q. How did you come to that four-tenths part per million?

A. Well, I think someone had simply added the PCB congeners and at the bottom of the page that's what they were as totaled.

Q. So, you didn't personally total them up?

A. No, I did not.

Q. Do you know whose handwriting that was that totaled them up at the bottom of the sheet?

A. No, I do not. I assume that coming up with 0.4 by simple addition is very simple and hard to make a mistake with, but I'd be happy to go over it with you if you'd like.

Q. Do you know if the results were reported in parts per million, parts were billion or parts were trillion?

A. The total that I recall for the PCB was four-tenths part per million and for the dioxins I believe it was in

parts per trillion. I believe it was lipid adjusted, but I'm not sure. It may not have been.

Q. Where did you meet Mr. and Mrs. Joiner?

[33] A. In Mr. Warshauer's office in Atlanta, Georgia.

Q. Why did you meet them?

A. I wanted to talk to them to get a feel for Mr. Joiner, to be able to have him describe to me what his exposure was in general, what his occupations had been like, what his chemical exposures might have been, what his medical history may have been to get a feel for what kind of person he was, whether he was a person I would find believable or not believable, to evaluate him and his cancer and to try to come to some conclusion as to the causation of his lung cancer.

Q. Was there any other reason for you to meet him?

A. Not that I can think of at this time.

Q. Now, you are an MD, is that correct?

A. Yes, sir.

Q. Did you physically examine Mr. Joiner?

A. I don't remember—I certainly did not do a complete medical exam or complete physical exam. I don't remember whether I did anything specific such as look at skin, I don't recall taking a blood pressure.

[34] Q. Did you take what some folks would refer to as your little black bag with you?

A. I don't recall doing that. But I could have and I might not have. I just don't remember at this time.

Q. Did you take his blood pressure?

A. I don't remember.

Q. Did you listen to his heart or lungs by means of a stethoscope?

A. I don't remember.

Q. Did you take his temperature?

A. No, I did not.

Q. Did you order any tests for him?

A. No, I did not.

Q. Why not?

A. Because he had a very thorough workup for his lung cancer and had been under intense medical care for a number of years when I saw him and I didn't want to put him through any more unnecessary hardship and I didn't feel the need for it.

Q. Did you take any notes during your meeting with Mr. Joiner?

A. I don't remember.

Q. You haven't presented any here today?

[35] A. If I have any, they are in my file and that was open to you yesterday and today.

Q. When you interview patients, do you typically take notes?

A. If I'm seeing someone as a doctor and they come to my office, and I'm seeing them for medical purposes, I take—I do a history and physical and make a note, yes.

Q. Did you do that for Mr. Joiner?

A. I did not feel I was seeing him as a regular patient. I was seeing him in an attorney's office on primarily a legal and medical legal matter.

* * * *

[36] Q. Other than that meeting in Atlanta and your meeting with Mr. Warshauer yesterday, have you had any other meetings face to face with Mr. Warshauer or the Joiners?

A. No, I did not.

* * * *

[38] Q. Other than Mr. Joiner's affidavit and his deposition transcript, and I believe you were also provided with a short three-line cigarette smoking history from Mr. Joiner. Other than those three documents, have you received anything else in writing describing Mr. Joiner's potential exposure history?

A. Not that I recall at this time.

Q. You made no notes that you recollect of your meeting with Mr. Joiner, is that correct?

A. Not that I recall at this time.

Q. Have you spoken with Mr. Joiner over the telephone at any time to ask him any questions?

A. Not that I remember at this time.

Q. So, have all of your communications, other than that face-to-face meeting, been with Mr. Warshauer or someone in his firm?

A. Yes, they have.

* * * *

[39] Q. You say Mr. Joiner was tired. You met with him just a few months ago?

A. Yes. I believe it was approximately a few months ago.

Q. This month is July of 1993, correct?

A. Yes, it is.

Q. So, you would have met with the Joiners in May or June?

A. I don't remember the date. Sometime this year, I believe. I don't recall the day.

Q. Was Mr. Joiner in remission when you saw him?

A. I don't know that I would use the term remission. He was a man who looked like he was going to be dead in less than a year. Whether his last cancer therapy had bought him a little extra time, perhaps it has, perhaps it hasn't. I don't know.

* * * *

[48] Q. Would it have been important to know whether other workers that he was around during the day smoked?

A. Well, it might have been of interest, but we had established that he had a smoking history for [49] many years and so did his parents.

Q. So, why would that have been significant to you?

A. Because most lung cancer in this country is related to cigarette smoking.

* * * *

Q. Setting aside the deposition for a moment, what do you recall he told you as an MD who was asking questions about his medical and smoking history?

[50] A. I recall that he came from a family of smokers. He smoked many years. He gave up smoking. He had other chemical exposures and he came down with lung cancer. That's how I saw it as an MD.

* * * *

[53] Q. Let me show you quickly what we've marked as Schecter Exhibit 10.

* * * *

Q. Did you assume that the social and personal history there given by Mr. Joiner to Dr. Morley was true?

A. With this is a brief note taken on a patient in acute pain with high temperature and is a very quick history. I have no reason to doubt that [54] he had a fever of 102 degrees Fa[h]renheit, small cell lung carcinoma, severe nausea, nasal discharge or he is allergic to Sulfa, Tylox and Codeine. And that his last chemotherapy ended on 1/92 for intensive treatment of small cell lung carcinoma stage III and that he remained disease free subsequently.

There is obviously a mistake in the family history which says negative for any evidence of carcinoma. The—that's clearly a mistake since we know his mother died of cancer. Positive for heart disease is correct. It states that the patient smoked one to two packs of cigarettes a day for 15 years. That seems a bit longer than I recall him saying he smoked, but I don't remember the year of starting or stopping. But two packs a day seems a bit higher. It's a quick history, a very short history done under acute illness, severe pain.

* * * *

[57] Q. His treating physician was Dr. Morley, one of them?

A. I presume so.

* * * *

[60] Q. Based on what you've learned in this case, what chemicals has Mr. Joiner been exposed to potentially?

A. What stands out after the cigarette smoke is the PCB transformer fluids and the PCB, dioxin and dibenzofuran contamination. And when I say dioxin and dibenzofuran, I'm referring to chemical contaminants or breakdown products which are frequently found in PCB fluids or in transformer fluids.

[61] Q. Any other chemicals that Mr. Joiner was exposed to?

A. Not that I know of or that I can recall at this time.

Q. Now, tell us what opinions you have reached in this case.

A. I believe more likely than not that Mr. Joiner's lung cancer was causally linked to cigarette smoking and PCB exposure. And by PCB exposure, I'm thinking also of PCBs and dioxins and dibenzofurans and related chemicals which frequently are found together in transformer fluids.

Q. Any-other opinion?

A. Well, that Mr. Joiner more likely than not has had a higher exposure or more exposure to transformer fluids and the chemicals in them than the average person, and this would include the PCBs, dioxins and dibenzofurans and related chemicals. And it seems to me from the history he's given, that until the mid-1980s, he was not aware of the fact that he was dealing with toxic chemicals and did not protect himself, nor did anyone attempt to protect him or inform him that he should be protected from these toxic chemicals. And this, of course, is a [62] breach of good occupational medicine or industrial hygiene practice.

Q. Any other opinions?
A. Not that occur to me at this minute.
Q. What do you mean by industrial hygiene practices?
A. I mean the practice by which workers are protected.
Q. By whom?
A. By government, by companies manufacturing toxic chemicals, by employers manufacturing toxic chemicals.
Q. Do you need any additional information in order for you to express these opinions?
A. Not that I can think of at this time.
Q. So, would these be considered your final opinions in this case?
A. Well, if there is further information that would alter them, then they might not be final. I don't hestitate in coming to these conclusions at this time. They seem to be reasonable.
Q. Do you plan any further investigation?
A. I haven't really thought about that.
Q. So, you've given no thought to any [63] additional investigation?
A. Well, I would think that if this isn't settled in a reasonable fashion and goes to trial, then one might want to be a little more thorough with Mr. Joiner, although I think I've covered the major basis more than adequately. And—
Q. You mean more thorough with his medical history?
A. Well, I might want to do a somewhat more thorough medical evaluations, although at this time, I really do not see the need for it. And I might want to visit the site of his employment and look at the transformers, look at the room involved, but I might want to examine medical [records] in more depth, although I don't see any point in examining the types of chemotherapeutic agents and their pharmacologic actions. I have sufficient knowledge for my purposes to know whether it would affect—know or not know as best anyone knows, how they might affect dioxin, dibenzofuran or PCB levels.

Q. Are you an analytical chemist?
A. No, I'm not.
Q. Do you know how to read a chromatogram?
A. No, I do not normally read chromatograms.

* * * *

[64] Q. Do you consider yourself an expert in oncology?
A. To the same extent that a Board certified physician in preventive medicine would be. No more, [65] no less for a licensed physician.
Q. You are not Board certified by any organization as an oncologist, are you?
A. As oncologist, no, I'm not.
Q. Ever practiced oncology?
A. No, I have not. In preventive medicine, we teach about the causes and prevention of cancer, but it is not my practice to see patients in oncology as an oncologist.
Q. Now, let's talk about your first opinion about the causal link. What facts do you base your opinion on that it's more likely than not that Robert Joiner's lung cancer is causally linked to cigarette smoking and exposure to PCBs and furans and dioxins, what facts is that opinion based on?
A. Most lung cancer in the United States is caused by cigarette smoking. And with cigarette smoking in the presence of other carcinogens, for example, asbestos or radiation, the rate of lung cancer will go up markedly. PCBs, dioxins and dibenzofurans are definitely promotors of cancer, that is, once a cell has been initiated, once the cancer has been initiated in the cell, then these chemicals definitely will promote the cancer. In [66] addition, in animal experiments by themselves, dioxins, dibenzofurans and PCBs cause cancer in a dose-dependent fashion. We can probably leave it there unless you want me to elaborate.
Q. Now, when you say that PCBs, dioxins and furans are definitely promoters, is that based on animal studies?

A. That these cause cancer is animal and human study. That they are promotors is based on in vivo and in vitro studies. The in vivo studies in animals show that these chemicals alone or following dosing with initiators of cancer will cause increase in cancers. The toxicity is also studying for these chemicals by a number of biochemicals means such as enzyme induction. And recent work such as that of Dr. George Lucier and colleagues at the National Institute of Health have shown that humans—human tissue appears to be as responsive as animal tissue to these chemicals, as laboratory rats, for example, which are sensitive species. The human studies are studies such as the Yusho poisoning where an excess of cancer has been shown in some studies. And Dr. Fingerhut's NIOSH study, some Seveso studies where humans were exposed to dioxins as published by [67] Dr. Bertazzi and others, IARC studies, International Agency on Cancer at the World Health Organization showing an increase in cancer in dioxin-exposed subjects and others.

Q. I want to go back. When you used the term promoter, are you talking about strictly animal studies?

A. These chemicals are considered a promoter based on evidence from laboratory studies.

Q. On animals?

A. On animals—primarily animal studies, yes.

Q. Whose studies are you relying on?

A. Many studies including that of Lucier and colleague. The studies I found, for example, many of them in the agency for toxic substances and disease registry toxicological profiles or PCBs and separate study or publication rather for dioxins and the separate publication for dibenzofurans where they've attempted to catalog the majority of the studies which strongly show that these chemicals are very powerful promoters.

Q. Again in animal studies, correct?

A. The—well, by animal studies, are you [68] excluding humans as animals?

Q. Yes.

A. You are refer to laboratory animals?

Q. Yes.

A. The studies for promoters per se have been primarily to date in animal studies. But human tissue has also been used for some studies of these chemicals and humans have been studied after exposure to the chemicals. But the difference is that we don't have the clear legally in this country to dose humans with toxic chemicals. The animal studies are far for powerful than the epidemiology studies where the sample size is smaller. We do not dose deliberately, so the dose is not known. The dose may be small. And latency periods cannot be followed as well as they can from animal studies or cell culture studies.

Q. Again, your opinion that PCBs, dioxins and furans operate as promoters is based upon studies of laboratory animals only, is that true?

A. The studies which tell us that PCBs, dioxins and dibenzofurans are promoters of cancer were developed through laboratory animals and we have belief that they are relevant to humans. We [69] test them on animals. We believe that's relevant to humans.

Q. Your opinion about PCBs, dioxins and furans being promoters is based upon studies of laboratory animals?

A. Yes. And my reason for believing this is relevant to human studies is because all government agencies concerned with health believe that this is the case and that we can usually pre-detect, because humans also are in the animal kingdom. Human cells are nuclei, cytoplasm, mitochodria, endoplasmic reticulum and respond in similar fashion.

Q. Object to the non-responsiveness to the answer after the word yes.

A. I would object to your keeping—stating that laboratory animals are different from human animals. I believe that we are in the same kingdom. That's what I've been taught. That's what I teach my medical students.

We do teach them that what is in animals is related to human.

Q. Object to the non-responsiveness.

Now, is it your opinion that cigarette smoking was the initiator of Robert Joiner's lung cancer?

[70] A. Well, that's an interesting question. We, of course, do not know whether the PCBs, dioxins and dibenzofurans also serve in an initiation function. One might—I would think that the cigarettes probably served as initiators and that the PCBs, dibenzofurans and dioxins probably more likely than not served as promoters of cancer. They may, in addition, also have served as initiators. These words aren't magical. They simply refer to whether the DNA is directly attacked or not.

* * * *

[71] Q. Based on your study in this area, what occurs when you administer the PCBs before the administration of the initiator in laboratory animal studies?

A. As I mentioned previously, PCBs alone also cause cancer, and this has been shown in many studies. They do not need to be—to have a promoter given first. So that PCBs, dioxins and dibenzofurans have been described as complete carcinogens by Dr. James Huff of the National Institute of Health because when given alone they will cause cancer to laboratory animals and probably to humans.

Q. Now, which chemicals are you speaking of there?

A. I'm speaking of dioxin and dioxin analogs which would include dibenzofurans, PCBs and other structurally very similar chemicals.

Q. Whose study was this?

A. The paper I just cited, and it was done by Dr. James Huff.

[72] Q. Did I understand you to say that this is all dose dependent?

A. These chemicals cause cancer in a dose dependent fashion.

Q. What is your understanding of the term dose dependent?

A. That means in simple language, the more you give, the more toxic outcome you get.

Q. Does it also mean that there is a threshold over which the chemical must reach in order to have any toxic effects?

A. No. As Dr. George Lucier and a Angelika Tritscher, George Clark and others have shown, a threshold is not implied nor is it necessarily found on biochemical responses with these chemicals.

* * * *

[75] Q. Let's move to your second opinion which was that in your opinion, Robert Joiner had higher exposure than the average person to [PCBs], dioxins and furans. On what facts do you base that opinion?

A. The fact that he worked with these chemicals.

Q. What other facts?

A. The fact that he worked with these chemicals for many years, he handled PCB contaminated transformer oil, he breathed smoke, he was in an underground enclosed area with no [76] protective gear for years. The rest of us do not normally handle chemicals contaminated with PCBs, dioxins or dibenzofurans as part of our work. That's not part of the work of the major population.

Q. What other facts do you base your opinion on?

A. Those are essentially the facts that I base them on, as I do normally in the practice of occupational medicine.

Q. Are there any other facts on which you can think of on which you base that opinion?

A. The documents we've discussed, my interviews with the patient and his wife, documents provided me by Mr. Warshauer and his colleagues.

Q. Now, your third opinion—

A. And I would perhaps even go a bit beyond that. I think it would be of less consideration than the others

opinion which usually a physician would come to the conclusion, the ones I've just given you. But the fact that this patient had a four-tenths—0.4 parts per million of total PCBs in his adipose tissue despite cancer chemotherapy, weight loss, weight gain after the exposure without protection and without customary protection against [77] toxic chemicals such as PCBs, dioxins and dibenzofurans, despite the fact that he still had 0.4 part per million of PCBs suggests to me that this is additional comformatory evidence for exposure beyond that of the average. Which we know he had because of his job.

Q. How many years did you assume Robert Joiner was exposed to PCBs, dioxins and furans?

A. I believe his exposure started on or about 1973, when I believe he started in the work, and continued at least until he began to wear protective gear and probably decreased in an amount—the protective gear was after that time in the mid-'80s.

Now, he may also, of course, have brought home these chemicals on his shoes and his clothes, as we know happens to workers exposed to chemicals. His clothes exposed to chemicals where we have the classical case of family members coming down with mesothelioma asbestos that the husband or father brought home on his clothes.

Q. Do you have any evidence to suggest that Mrs. Joiner has had any adverse health effects from PCBs, dioxins or furans?

[78] A. No. At this time, I have no evidence that that is the case. However, I believe it is probable that chemicals were brought to the home on shoes, on the clothing, on the skin of Mr. Joiner in those years when protective gear was not used and that there may be an increase in these chemicals in the home, or there may have been during those years.

Q. Looking at the affidavit of Robert Joiner, did you assume based on his affidavit that he would have had

roughly ten years of exposure without the use of any protective equipment?

A. Well, if he started in 1973 and somewhere after ten years began to wear protective equipment, I assume that he had exposure during those unprotected years.

Q. Now, during those unprotected years, how do you quantify his level of exposure?

A. There is no way of quantifying what has entered his lungs which is where he got the cancer and where it is the site of PCB metabolites. This is where PCB metabolites congregate and deposit. I assume that—it seems highly logical to me that he breathed PCBs, dibenzofurans and dioxins and so, there was an immediate passage through the lung [79] cells and to a certain extent deposition. We have no way of quantifying dose and target organ from that kind of exposure. There is no method that I know of published in the medical literature which would allow us to do that.

Q. So, you have no opinion as to the level of PCB, dioxins or furans in Mr. Joiner's lungs?

A. I have an opinion that it is above that which the general population would be exposed to.

Q. But again, you cannot quantify that, can you?

A. The exact amount, no, I cannot quantify the exact amount.

Q. What is the general background level for PCBs in the general population?

A. I'm sorry.

Q. What is the general background level in adipose tissue for PCBs?

A. In Americans?

Q. Yes.

A. The most recent findings I've seen are those of the Yosmeas which suggest that the levels in the last decade have gone down from roughly 1.2 parts per million in adipose tissue to roughly [80] 0.4 parts per million for the average adult in adipose tissue.

* * * *

[82] Q. In the United States in the last 20 years, have PCB fat levels usually been .5 to 1.5 part per million in fat for the general population?

A. Well, I don't know that the figures—just reviewed the EPA's PCB tissue levels in the last few months and that's not the data that was presented in their summary of adipose tissue levels for PCBs for the United States. I don't know what you are citing and I don't know whether that's correct or not correct.

Q. Now, what is the general background level in the United States for dioxins and furans in adipose tissue?

A. Are you asking for a specific congener?

Q. I'm asking for total, the accumulation of all of the congeners.

A. Total dioxins and dibenzofurans in adipose tissue, breast milk or blood on a lipid basis is roughly 12 to 1,400 parts per trillion.

Q. Do you recall what Robert Joiner's level was as revealed in the Triangle Laboratories data?

A. No, I don't recall the level.

* * * *

[83] Q. That does assume some form of actual intake, does it not?

A. Yes. Which everyone in the United States has. Or in any country I've ever tested people in so far in these industrial times.

Q. Is there any other published data that you use to determine background levels for the general population other than what you've already told us?

[84] A. My general knowledge of the field, attending meetings, reading the literature, talking to colleagues.

Q. Do you agree that if an individual's levels in fat tissue for furans, dioxins and PCBs are below background levels, it is more likely than not that the individual will not experience any adverse health effects?

A. No.

Q. What information do you have about the concentrations of PCBs, furans and dioxins in the mineral

oil contained in the transformers that Robert Joiner worked around?

A. We have specific data back that came by fax yesterday, and I showed you my entire file, showing that there were PCBs in some of the mineral oil. And my general knowledge that dibenzofurans and dioxins are found in PCB-containing electrical transformer oils.

Q. Now, you said some of the transformers. How many of the transformers that you have information on actually contained PCBs?

A. Some did and some didn't. I didn't attempt to add them up.

[85] Q. What was the level of concentration?

A. It varied from a few parts per million up to a few hundred parts per million in those that I looked at that came in yesterday.

Q. Do you recall seeing any that were greater than a few hundred parts per million?

A. I don't remember. I didn't look at every page.

Q. Did you see any record that indicated any of these transformers contained pure Aroclor?

A. No, I did not.

Q. From any source, do you have any information that any of these transformers that Robert Joiner worked on had pure Aroclor?

A. No, I do not.

Q. Do you have any information from any source that any of the transformers that Robert Joiner worked on had a concentration of Aroclor as high as 650,000 parts per million?

A. No, I did not.

Q. Now, the test certificates or the information that was sent to you yesterday, did it show testing for any substance other than PCBs or mineral oil?

[86] A. I didn't notice.

Q. Have you seen any information from any source that showed any content for dioxin or furans?

A. No. Not for these specific oils. I have, of course, for others.

* * * *

Q. Is it essential in the practice of medicine and in clinical research that a distinction be made between potential exposure to a toxic chemical on the one hand and actual intake of that chemical into the human body on the other hand?

A. That is a useful distinction.

Q. Why is it useful?

A. Because actual exposure can lead to health consequences whereas the potential for exposure without actual intake would not lead to a physical deterious effect.

Q. Isn't it also true that the fact that you [87] may be exposed to a chemical does not necessarily mean that you have taken it into your body?

A. Of course. But if a chemical is in the air, it's very hard not to breathe. I can choose whether I want to drink the coffee in the cup in front of me, but I cannot choose what's in the air that I may wish to breathe or not breathe.

Q. Is it possible to distinguish between potential exposure on the one hand and actual intake on the other hand by determining the tissue level of the toxic chemical in the fat in the exposed person and then comparing that level with those of the general population?

A. It sometimes can be useful. It's one medical test that one uses in coming to a medical conclusion, but one never should practice medicine based on one test alone. And it can also be not useful.

* * * *

[89] Q. Do you know Mr. Joiner's rate of [90] absorption to a reasonable degree of medical certainty?

A. I haven't thought about it for him. You are talking about PCBs or dioxins?

Q. All three.

A. I hadn't really thought about that up until this time. At this time, I have no opinion.

Q. Do you know to a reasonable degree of medical certainty what his metabolic rate of clearance is for PCBs, dioxins and furans?

A. Well, I don't think that information is available for anyone, let alone Mr. Joiner.

Q. To a reasonable degree of medical certainty, do you know his sensitivity, that is Robert Joiner's sensitivity, if any, to PCBs, dioxins and furans?

A. Yeah. We don't have any good methods of estimating genetic sensitivity. Except by the response such as enzyme induction or the formation of cancer which he has, so my conclusion was that these chemicals played a certain role in the promotion of his cancer and that he has a certain sensitivity to them.

Q. What is it, do you know?

[91] A. He is sensitive.

Q. How do you know that?

A. Most people are sensitive, most animals are sensitive. We have a voluminous data on human response in Yusho and Yuchem to humans exposed to PCBs, dibenzofurans and dioxins.

Q. Now, in those two incidents, the Yusho and the Yuchem, in both of those incidences, what was the concentration of PCBs, was it a 65 percent concentration, was it 650 parts per million Aroclor or some equivalent?

A. I don't remember what it was. It was PCB and dibenzofuran and dioxin contamination of rice oil which was used to cook food. I don't think anyone can be certain of what the intake was.

Q. Do you know of any animal studies that have ever been conducted by anyone where the test substance that was given to the animal had a dose of 500 parts per million PCB?

A. I don't recall what the dosage used in the very many studies of PCBs have been. You are referring to animal studies?

Q. Yes.

A. There would have been a huge number of [92] studies.

Q. In all of those studies, hasn't the dose that's been administered to the laboratory animal been far, far in excess of 500 parts per million, dramatically higher?

A. As I said, I don't have the doses memorized. What I can do would be to tell you that Peterson's recent study of central nervous system damage, reproductive damage and nerve damage even the smallest dose of two, three, seven, eight TCDD given to the mother caused damage to the offspring, brain damage, cognitive damage, emotional damage, hormone damage to the offspring. And I also know that in the Lucier, et al, experiments at the National Institute of Health, the biochemical end points they examined showed no sign of a threshold. The smaller the amount given, there was still a small response. It did not seem to taper off to 0.

Q. What was the dose of the two, three, seven, eight TCDD given in those studies?

A. I don't have it memorized. It's easy to look up.

Q. Now, you moved from PCBs to dioxin. Let's go back to PCBs. Do you know of any [93] studies—any laboratory animal studies where the dose that was administered was as little as 500 parts per million?

A. I do not have any of the doses memorized for the voluminous PCB animal and cell culture data. I don't have any of them memorized.

Q. As a research scientist, you don't have any idea whether the dose given to those laboratory animals is far, far in excess of 500 parts per million, you just don't know despite all of your reading over all of these years?

A. 500 parts per million doesn't tell you anything if you are given one drop versus one gallon of something. You are giving me a—one part or 500 parts in a million parts of something else. You are not telling me what the total dose is, so it's not a real number. You are not saying, Dr. Schecter, do any PCB animal studies use more than .6 picogram per kilogram per body weight given five days a week or seven days or week or given one time. You are asking the question in a very strange fashion and

I certainly have not memorized that. And in my library I have voluminous reviews of the PCB animal data. We can certainly do that if you [94] would like to do that this afternoon or tomorrow. I certainly make no attempt to memorize the many, many toxicology experiments that are relevant to this field.

Q. In any of the animal studies in which you base your opinion in this case, do you know what the dose was that was administered to the animals?

A. Do I have any memorized at this time, no. At this time, I have made no attempt to try to review or memorize the dose, including those where I have done part of the toxicology myself and have been a co-author on the studies. I think it's silly to say do you remember whether it was .2 picograms per kilograms or .8. I don't remember.

* * * *

[107] Q. Do the levels in human adipose tissue for higher chlorinated PCBs remain relatively constant for several years?

A. The total level or the congeners?

Q. The congeners.

A. Well, if you are asking did a higher PCB levels—are they excreted slower than lower ones, the answer is yes. If you are asking for specific congeners, I'm not sure I know the answer. And again, as a rule of thumb, I'm going to say yes.

* * * *

[112] Q. Now, are you aware of any animal studies that have been done on mice that would suggest that PCBs are a potent anti-carcinogenic agent?

[113] A. There are studies which would show—which found less tumors of a certain kind in animals exposed to PCBs or to dioxins than in controlled animals under the circumstances of the experiment.

Q. In other words, instead of being a promoter, it was an inhibitor?

A. That could be one interpretation. Another interpretation is that it's a statistical fluke. The sample size

was inadequate—this is something that's been considered and studied in many laboratories.

* * * *

[114] Q. Now, you mentioned back early on this morning about Mr. Joiner's work history, that there were lights that were used to heat the cores. Do you remember that testimony?

A. Yes, sir.

Q. All right. What temperatures are you assuming, for purposes of your opinion, those field lights caused the cores to reach?

A. Now, I'm not certain how hot the temperature was.

Q. So, you don't have an opinion?

A. No. I recall that he said the paint was blistered off, occasionally would turn red hot, but I don't know what that temperature is.

Q. Do you agree that laboratory studies have established that the paralysis of chlorobenzene at temperatures of at least 600 degrees centigrade with yield dioxins and furans?

[115] A. Yes. And they've also established it at lower temperatures.

Q. How much lower?

A. Well, that's a subject of debate. Incinerators seem to be producing it as the temperature goes lower on the way out. But that's certainly been well-documented.

Q. Do you agree that laboratory studies have studied that for paralysis of PCBs again you have to have temperatures of at least 600 degrees centigrade to produce furans?

A. No. Your statement is not correct.

Q. What minimum temperature is necessary?

A. I don't know the minimum temperature, but in 200 to 600 degree, you get a yield of PCBs being empirically converted to a reasonable larger yield of dibenzofurans and a somewhat smaller of chlorinated dioxins and the chlorinated benzenes of which you spoke

previously. Again, in the 200 to 600 degree centigrade temperature will produce a yield to greater or lesser extent of chlorinated dioxins and/or dibenzofurans.

* * * *

[118] Q. What's the minimum temperature there to create furans?

A. They are hot.

Q. What's the minimum temperature which they are produced?

A. Again, we don't know the lowest level.

Q. It's well above 200 degrees centigrade, isn't it, way above 200 degrees centigrade?

A. The question is at the hottest part you do try to keep the waste incinerators very hot to dry toxic chemicals. But as you go out of the flame, out of the heated area, you go through an area which is much cooler and there is a production of dioxins and dibenzofurans according to current research in the field.

Q. But do you know what that temperature is?

A. The lowest temperature, I don't know what the lowest temperature is.

* * * *

[127] Q. Was Mr. Joiner's level of dioxin found by Triangle Laboratory well below background levels?

A. Triangle Laboratory had a major problem for doing this. I give no credence to their results. They are not a World Health Organization. They did not take part in this round robin tests. And in any good laboratory result in human tissue, you should at least have a recognizable level for each of the 16 usually reported dioxins or dibenzofurans, and usually they had nondetect. Which to me indicates they had a great deal of trouble in laboratory methodology.

Q. Let me object to the responsiveness of the answer and ask the question again.

Wasn't the level of dioxin found in Robert Joiner's adipose tissue sample by Triangle Laboratories lower than the general background level? Either it was or wasn't.

MR. WARSHAUER: Object to the form of the question because it requires him to rely on a test result—
[128] A. My answer is garbage in, garbage out. They obviously have major problems with that laboratory analysis and I was a physician who is very experienced in that field and can give it no credence whatsoever.

Q. Was the number which was reported below background levels?

A. If the lab obviously had a major methodologic problem, I wouldn't use that in coming to a conclusion.

As we mentioned earlier, we described the numbers that I think are average for the United States, but that means you get results, you have a good lab doing good results. And as you know, the lab error for dioxin laboratories is subsequently generally about 25 to 40 percent plus or minus. But you should have a number. You shouldn't have nondetect.

Q. In your article in the Banbury report, did you publish a table that had the dioxin and dibenzofurans in whole blood from various countries in parts per trillion and it was recorded for the United States?

A. Well, yes, I did.

[129] Q. What did you report there for dioxin?

A. I reported—and again, we had only one nondetect. At an extremely low level of 16 or so congeners we looked at, we had a total of 1,591.

Q. What about for the furans?

A. I'm sorry. I thought you were asking me for both. I misspoke if you were—

Q. Dioxins?

A. For dioxins in this series, A pool of 100, I reported 1,499 parts per trillion in the lipid.

Q. What did you report for the furans?

A. And for the furans I reported 92 parts per trillion. But again, I must emphasize if I as a physician see a laboratory report that comes back to me obviously with a mistake made or no values, I do not treat a patient or evaluate a patient based on that. If a laboratory test is in error, you ask to have it repeated or you ignore it.

Q. Object to the non-responsiveness to the answer.

Do you know of any animal studies on respiratory effect in laboratory animals after inhalation exposure to PCBs, dioxins or furans?

[130] A. There are very few, if any, laboratory tests that have been done on animals with respect to respiratory toxicology of dioxins, dibenzofurans and PCBs. And I do not remember the content of the section on respiratory toxicology and the toxicologic profiles which I reviewed in the last year. I don't recall that at this point, if there [131] were any. I know that they are extremely sparce, if any.

* * * *

Q. Do you know of any animal studies on cancer in laboratory animals after inhalation of exposure of PCBs?

A. I don't recall any at this time.

* * * *

[133] Q. Does the dilution of PCBs in mineral oil reduce or inhibit the formation of furans if the mineral oil solution which has PCBs in it is heated? Do you know if the presence of the mineral oil inhibits or reduces the formation of furans?

A. I don't recall any studies that I have [134] read addressing that issue.

* * * *

[137] Q. Getting back to a line of questions that Mr. Cochran asked you earlier relating to PCBs, furans and dioxins contained in mineral oil or transformer fluid, you had given an analogy in answer to one of his questions about it being unknown at what point each of these substances—what the low end of the point of each one of these substances would vaporize. Do you remember that testimony?

[138] A. I don't think that's what I said. I think I said that on the vaporization question I didn't have the point memorized, but on the—in converting in heat and in the presence of oxygen in the PCBs converting to dibenzo mostly and dioxins, to a lesser extent, I believe that it's still subject to scientific research as to what the lowest temperature that will happen.

Q. Can you tell me at what point a PCB vaporizes?

A. No, sir. I haven't attempted to memorize that.

Q. Is it a very high number like 600 degrees centigrade?

A. That's the kind of thing I just look up when I need it. I just don't memorize that kind of data.

Q. It's well above the point that water boils, is it not?

A. I don't even try to memorize that data.

Q. Do you know what temperature water will vaporize?

A. I mean, sure, I would agree with you. First of all, I don't memorize temperatures, I don't [139] memorize numbers. I try not to do that unless it's something I use every day. If I can look it up in a couple of minutes, I'll look it up. It doesn't vaporize—it doesn't evaporate very easily. If that's the point you are getting at, I agree with you there.

* * * *

[143] [Q.] I'd like to know the percentage of time over the last ten years beginning at the year furthest away that you have spent seeing patients.

A. I don't know what that is. It would probably be less than 10 percent now and over the last ten years.

* * * *

[145] Q. Are you presently seeing patients?

A. I see a small number.

Q. How many, for example, are you going to see this week?

A. This week I'm not going to see any.

Q. Last week?

A. I didn't see any last week.

Q. The week before that?

A. Well, didn't see any the week before that.

Q. Did you see any during the month of May?

A. I think I saw several. I don't recall.

Q. When you say several, is that between five and ten or five and nine or four and nine or what?

A. Well, several means less than five to me.

Q. Do you recall what sort of malady or [146] condition the patients that you saw came to you for either examination or treatment?

A. I try to discourage patients in coming to see me except in any occupational problems. I try to expose chemical exposure other than the chemicals I'm interested in and those are PCB, dioxins, dibenzofurans, DDT.

Q. For each of the patients that you saw in May, were they for the purpose of evaluating what a particular chemical had done for them or had not done to them?

A. The last patient I saw were follow-up patients after chemical exposure.

Q. Were each of the patients that you saw involved in some sort of litigation or anticipated litigation?

A. The ones in May were.

* * * *

[150] Q. This morning I noticed that a check was delivered to you for, I think, $2,800 for today's time?

MR. COCHRAN: $2,600.

Q. $2,600 dollars for today's time?

A. That's correct.

* * * *

[161] Q. You count this as an eight-hour day?

A. This is a full day that's tied up.

Q. So that's about $325 an hour?

A. I didn't do it that way. But if you tell me that's what the arithmetic is, I certainly won't argue.

Q. What's your salary from the State University of New York?

A. $87,000 plus fringe benefits.

Q. If you work 24 days a year—25 days a year, that's 65,000 in litigation consulting fees?

A. With no fringe benefit, no pension, no health insurance, no sabbaticals and so on.

* * * *

[166] Q. How old is Mr. Joiner?

A. Approximately 39.

Q. So, if he smoked for 15 years and started when he was 18, that would make him 33. Which is not 1980, according to my calculations. So, does that change your opinion in any way?

A. I would say the conclusions—the conclusions that we discussed earlier?

Q. Yes.

A. As I recall, we had four conclusions. Can we run over them one at a time and do them one at a time because they may be different in one but not in the other and I just don't remember them at the moment.

Q. Opinion number one is that Mr. Joiner's lung cancer was caused by cigarette smoking and PCB exposure.

My notes may not be as exactly what you said, and then I've got including dioxins, furans and related chemicals.

A. I think my conclusion would be the same on that one.

* * * *

[168] Q. Your opinions do not change in any way whether he smoked for eight years or 15 years and whether he smoked one pack a day or two packs a day?

A. My conclusion is the same as what we just said a minute ago.

Q. Now, also, you said that he was exposed to more PCBs than the general population, do you remember saying that?

A. Yes.

Q. How much more?

A. Well, I told you that I don't think anyone can quantitate it and that I really don't think I or anyone else can quantitate it. I can say, it's in excess of what he would have consumed had he not taken it into his body if not for this job and this scenario that we discussed and it's more than the general population.

[169] Q. How much more?

A. I don't know.

Q. 1 percent more?

A. I don't know. I don't think anyone can come up with that and one of the big problems is you do not know how much got into the target organ because certainly he breathed some PCBs, dioxins and dibenzofurans from this job, but what the amount is is in question. But some of it went directly through the lung tissue to get into the bloodstream and the lung tissue is generally a target organ. PCBs—and specifically, he has personally come down with lung cancer.

Q. Are you saying that he came into contact to these PCBs through ingestion, dermal contact or breathing of vapors?

A. By ingestion, gastrointestinal tract?

Q. Yes.

A. It would seem to me that he ate food without necessarily cleaning his hands and the food almost certainly on some occasions was contaminated with an excess of PCBs and dioxins and dibenzofurans from his job. And number two, he breathed without protective gear. Heated and unheated transformer [170] oil which, in some cases was contaminated with PCBs and if PCBs, almost certainly dibenzofurans and dioxins. And third, he did not protect his skin from that, so his hands and face and neck and shoes and feet almost certainly got some transformer oil.

Q. You are saying all three?

A. Yes.

Q. How much, can you give us any idea of quantity? Is it 1 percent more than the general population or 100 percent more or how much?

A. I don't think it's scientifically possible to come up with a good estimate, and particularly with respect to the target organ that we're most concerned with, how much got into the lung.

Q. Now, you've also said that the Triangle Lab report which showed his body burden—

A. Which did not show his body burden.

Q. You said it was defective. How was that test ordered?

A. I have no idea.

Q. You said that as a scientific—when you see a test that you don't think is reliable, you repeat it or you ignore it?

[171] A. Well, as a physician. First of all, I happen to be one of the people, the physician scientist who develops this kind of testing in humans in America. And so, I have a fair amount of experience as to when this looks believable and when I tell a chemist, you guys have goofed.

Q. Did you repeat it or did you ignore it?

A. The dioxin, dibenzofuran portion of that test in my professional judgment is clearly in error.

Q. Did you repeat it or ignore it?

A. I didn't order the test. The test was ordered by a law firm.

Q. What law firm?

A. I presume it was your law firm (indicating).

Q. So, you ignored it?

A. I didn't ignore it. I just told the folks who had ordered it that I didn't think you ought to be relying on this for anything. The dioxin, dibenzofuran portion.

Q. But you did rely on it for purposes of the PCB level?

A. I came up for the conclusion to answer [172] certain questions I was asked this morning. That particular laboratory is well known for doing environmental testing, soil and so on.

* * * *

Q. You said the test showed four parts per million?

A. Four-tenths. This is from memory.

Q. This was in the range of what one would normally expect?

[173] A. This is what you would expect from an average North American population of healthy adults if done by the same technique that Yosmeas uses where he came up with the survey where his survey showed that the

PCB levels in fat tissue are decreasing and they are now down to by coincidence I think, it was approximately four-tenths part per million.

Q. The same shown in the test by Mr. Joiner?

A. Yes. But Mr. Joiner has lost a lot of weight and gained weight and has extremely traumatic chemotherapy and radiation therapy. My assumption is that his level of PCBs is diluted from what it was prior to the loss of weight and gaining of weight. And I also don't know what his level was prior to exposure to PCBs.

Q. I heard you say that, but I also heard you say that you don't have any studies or empirical evidence which show that there is a reduction in the PCB level caused by weight loss and subsequent weight gain or by chemotherapy.

A. I was referring to dioxin and dibenzofuran where is concern. And I said that the—

[174] Q Would you say PCB—

A. Also, let me finish the logic. In thinking that this four-tenths might possibly be in conjunction with the medical and exposure history evidence of higher than expected levels. He lost weight. He lost fat. Lost a large amount of fat. Fat has the highest concentration of PCBs, dioxins and dibenzofurans. These are fat soluble. If you lose fat, probably you are losing—and you lose it for a period of time, probably you are losing PCBs, dioxins and dibenzofurans. If you then regain from new food the fat and the weight, you are probably diluting.

Q. I heard you say that. My question was: You don't have any empirical evidence of that, you are just making that hypothesis, there is no evidence or proof of that of any kind?

A. Not entirely. For example, without any doubt that in nursing mothers, when the fat goes down due to nursing, the mother loses her fat due to giving it to the baby in the milk. We know that her dioxin, dibenzofuran and PCB level goes down as she nurses. And her levels are frequently found to be on average lower after nursing one baby and then the [175] second baby. That's been

published in the work of Furst. We do have evidence as to loss of fat, the dioxin and dibenzofuran and literature is not so clear. There is some old PCB data which suggests that maybe alteration—but because the PCB methodology has changed and also because I don't remember the details of all the published literature, I can't cite you anything that I would rely that has been published that I think is worthwhile to answer that question.

* * * *

[176] Q. Doctor, I just have a few more questions I'd like to ask following up about your scientific methodology.

As part of your opinion, are you assuming that the heating of the transformer cores created furans or dioxins, are you assuming that?

A. I'm assuming that where PCBs were present, and they were present in some of these cores, I believe there probably was a certain degree of formation of dibenzofurans and dibenzo—dioxins. I'm also assuming that in general, it's my understanding of what we know in the field that as PCB containing transformer fluids are used, that there is a certain chemical change of PCBs and an increase in dibenzofurans and to a lesser extent dioxins.

Q. But did I understand you to say you don't know the temperature that's necessary, the minimum temperature that's necessary to create furans and dioxins from the heating of PCBs, you don't know that number, do you?

A. I don't recall what the lowest published [177] number at this point is and as I told you, it's my understanding of the literature that it's still an active topic of scienific chemical-type research as to what the lowest level would be. I don't think it's so much in doubt that PCB containing transformer oils do usually contain dibenzofurans in normal. I think that's well established. I believe it's fairly well established that there is a gradual increase of the dibenzofurans in PCB containing transformer oil.

Q. And do you know what the temperature of that would have been created by the lights, you have no idea?

A. I don't remember whether it was discussed or I went over, but at this point, I don't recall what the temperature might have been.

* * * *

[178] Q. Did you assume there was any inhalation by Mr. Joiner of PCBs, furans and dioxins when the dielectric fluid was merely at room temperature?

A. Yes, I did, that there was some, yes.

Q. But again, you don't have any idea how much?

A. I cannot quantify nor do we know which congeners were necessarily present nor their relative toxicity because we don't have the chemical data. And we don't—certainly don't have any congener data from the environmental samples on PCBs, dibenzofurans or dioxins that I'm aware of. And one other point that you brought up, the dioxin toxic equivalent as they relate to PCBs. Many of them are still in question, so even if we had the [179] analytic data, there would be a certain amount of uncertainty as to the health consequences.

Q. As a general manner, do you agree that a fat biopsy will reflect not only the level at a given time, but will also reflect exposure for a certain period of time in the past depending on the congeners identified?

A. Would you please read that again a little slower?

Q. Do you agree that a fat biopsy, that is, one done on adipose tissue, will reflect not only the level at a given time, but will also reflect exposure for a certain period of time in the past depending upon the congeners identified for PCBs, dioxins and furans?

A. Well, it can. Although, I'm a little puzzled as to why you added the last phrase in your question. It was almost easier to answer before you added that, but it can. It can reflect under certain conditions and especially average absorption, average excretion, whatever that may be, correct time of sampling, excellent lab and a healthy adult patient.

* * * *

JOHN D. ARCHBOLD MEMORIAL HOSPITAL

Gordon Avenue at Mimosa Drive
Thomasville, Georgia 31792

HISTORY AND MEDICAL DR. MORLEY
Page 1

JOINER, ROBERT
MR# 235149 HOSP SVC: ONM
PT# 102095817 529 1

ADMITTED: May 10, 1992

CHIEF COMPLAINT: Mr. Joiner presented to the clinic with fever of 102 degrees Fahrenheit, small cell lung carcinoma, and severe nausea which has been present for several days. He has had significant nasal discharge with daily fevers, and presents for admission.

PAST MEDICAL HISTORY: He is allergic to Sulfa, Tylox and Codeine. He has had no major illnesses. Last chemotherapy ended in 1/92 for intensive treatment of small cell lung carcinoma stage III. He has remained disease free subsequently.

FAMILY HISTORY: Negative for any evidence of carcinoma. Positive for heart disease.

SOCIAL & PERSONAL HISTORY: Negative for cigarettes and alcohol use, although the patient did smoke 1-2 packs of cigarettes a day for 15 years.

PHYSICAL EXAMINATION: GENERAL: The patient is alert and oriented, but is complaining of severe nausea and vomiting, and is doubled-up because of abdominal cramping pain. NECK: Reveals no adenopathy or chyromegaly. HEENT: Reveals Horner's syndrome of left eye as before. The rest of the cranial nerves are essentially within normal limits. CHEST: Clear to ausculta-

tion and percussion bilaterally, although left lung sounds are decreased as previousy, because of surgical changes and radiation fibrosis. ABDOMEN: Diffusely nontender, with no organomegaly or masses, and normal bowel sounds. EXTREMITIES: With no clubbing, cyanosis or edema. LABORATORY: Pending.

IMPRESSION:

1. A patient with small cell lung carcinoma stage III, in remission.

PLAN:

The patient will be admitted to rule out recurrent disease. IV antibiotics will be administered because of fever, and fever work up will be obtained.

/s/ W. B. Morley
W. B. MORLEY, M.D.

RBM/plr

5/9/92 @ 5:48a
5/10/92 @ 4:17p

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

Deposition of DANIEL T. TEITELBAUM, taken on behalf of Defendant General Electric Company, pursuant to Notice of Taking Deposition in the above-entitled action, on Tuesday, October 12, 1993, at 10 a.m., at 3306 Independent Square, Jacksonville, Florida, before Shelli Kozachenko, CSR, RPR, and a Notary Public in and for the State of Florida at Large.

* * * *

[4] DANIEL T. TEITELBAUM,

having been produced and first duly sworn as a witness, testified as follows:

* * * *

[8] Q All right. Now, who prepared these, if you know?

A One was Joanne Milavec, and the other one was Nancy Fitzgerald.

Q All right. Who are Joanne Milavec and the other lady you just—Nancy Fitzgerald?

A They're two employees in my office.

Q And Joanne Milavec, then, is a paralegal?

A Yes.

Q Is she a full-time employee?

A Yes.

* * * *

[17] Q In reaching your opinion, are you assuming that there's been more than one fire?

A You don't know even what my opinion is, and I don't know what opinion you're referring to, so when you get around to it, why don't you ask me that question and I'll try to answer it for you. I really don't know what opinion you're talking about.

Q How many fires are you aware Mr. Joiner worked on, around, or near where the substance which caught fire contained PCBs?

A Well, Mr. Joiner describes in his deposition, and told me that in the early days of his career, he burned transformer oil, but he didn't keep a diary of [18] how many times, so I really wouldn't have any way of answering that question.

Q Okay. Anything other than that that you can recall—

A No.

Q —he told you about fires?

A I'd have to look at my notes and see what I have there. He did mention several occasions where there were transformer—

Q All right. Here are your notes. If you would—

A —fires.

Q —would you recount those for us, please? Would you mind if I came over there so I could read over your shoulder?

A Yes, I would mind. Let's make a copy, and then it will be easier.

Q Just put it here on the table between us, so we can read it—

A Well, I can't. I'd really—my eyes are such that it's just much more comfortable if I read it that way. Why don't we make a copy and then you can have a copy, and I can have a copy.

Q All right.

* * * *

[21] Q When you met with Mr. Joiner on July the 14th of 1993, did you conduct a physical examination of him?

A Yes.

Q What did you do?

A There's a notation of physical examination. I did as complete an examination as one could do not [22] working in one's own office, but actually there was pretty much everything that I needed, and so I did a typical examination just as—about the same as what I would have done had I had him in my own office, took his vital signs and went through and looked at him. I did not do any laboratory work, but I did enough of an examination to know what his condition was at the time that I saw him.

Q All right. You say you didn't do any laboratory work. Did you order any blood tests?

A No.

Q Any other diagnostic tests?

A No. He's had a very large amount of laboratory work, most of it quite recently. There was no reason to do that.

* * * *

[24] Q Have you seen a videotape of Mr. Joiner's work area?

A No, I actually didn't know about that until after I read his deposition, and I've not seen it, no. But it does correspond, from the description he gives in his deposition, to what he told me in his narrative history, apparently. Dr. Schecter describes it in some detail, and it sounds about the way it was described to me.

MR. COCHRAN: Object to the nonresponsiveness to the last half of the answer.

Q If you've never seen the videotape, how do you know that it corresponds to anything?

A Well, Dr. Schecter describes it. I don't know who took his deposition, whether it was you or not, but whoever it was went into a great deal of detail about it. And from the description which is there, it sounds very much like what Mr. Joiner told me his workplace looked like, so that's what I know about it.

Q Have you ever visited Thomasville?

A No.

[25] Q How many times have you met with Mr. Joiner?

A Just once.

Q Other than Mr. Joiner, have you had any conversations either face-to-face or over the telephone with anyone that has ever worked with Mr. Joiner?

A No.

Q Have you ever seen the analysis done by Triangle Laboratories?

A No, and the only thing I know about it is what Dr. Schecter discussed in his deposition.

Q Other than the adipose tissue sample that was tested at Triangle Laboratories, do you know of any other adipose tissue or blood samples taken from Mr. Joiner that have been tested?

A No.

* * * *

[27] Q Have you had any conversations about this case with a Dr. Julian Loube, L-o-u-b-e?

A Never heard of him.

THE WITNESS: What was that, L-o-u-b-e?

MR. WARSHAUER: B as in boy.

THE WITNESS: Just B, L-o-u-b?

MR. WARSHAUER: E.

THE WITNESS: Who was that?

MR. WARSHAUER: Just a treating physician in this case.

THE WITNESS: Okay. An M.D.? I'm sorry, I just wanted to make a note. It was not someone I'd ever heard of.

BY MR. COCHRAN:

Q Have you had any communications with any of [28] Dr.—or Mr. Joiner's, excuse me, treating physicians?

A No.

* * * *

Q All right. If you would, Dr. Teitelbaum, would you simply tell us what opinions you have reached in this case?

A Yes. I would say I have three opinions. The first opinion is that to the best of anyone's diagnostic capacity,

Mr. Joiner had lung cancer and has been treated and is currently in remission from that lung cancer.

Secondly, it's clear that for a period of many years, Mr. Joiner worked as an industrial electrician and had exposure to various materials commonly used in that trade, including mineral oils contaminated with PCBs.

And, three, that his lung cancer was caused by or contributed to in a significant degree by the materials with which he worked.

* * * *

[29] Q All right. Let's go to number two. Tell me each and every fact on which you base your opinion that he had exposure to mineral oil contaminated with PCBs.

* * * *

A Okay. In Mr. Joiner's history and in his deposition, he indicated that he began to work as an electrician for the City of Thomasville in June of 1973. He describes repeatedly in his deposition—if I could, can I have the medical chart? I need the . . .

Q (Tenders document.)

A In the form he completed which is indicated in my chart as occupational/environmental history form, he has circled all of the materials from the list that I present to each patient with which he worked, and he has handwritten PCB transformers as one of the items with which he worked.

[30] In his deposition he describes many years of work with mineral oil-filled transformers which he learned later in his career, following EPA investigations of the site, had been on occasions contaminated with varying concentrations of mineral oil—excuse me, with varying concentrations of PCBs.

He describes in exquisite detail, both in his narrative history to me and in his deposition, the many kinds of work that he did, including the draining of that oil, the transfer of the oil to various kinds of drums, the refilling of transformers, and the awareness which he developed

of the PCB contaminations after the EPA became involved in the control of PCBs.

He puts the date that he became aware of this as sometime between 1985 and 1987 when he stated that he attended an EPA class to learn about PCBs.

Q Where did he say that?

A On page 98 of his deposition.

Q All right. Go ahead.

A He states that sometime in that period, the city began to furnish gear, including Tyvek suits, overshoes, full-face respirators, and so on, but he himself—he stated there that he denied that that was because the EPA was pushing it. So I can't tell from the discussion what he actually knew, but he does state [31] specifically that he learned about PCBs when he went to the class.

So that's fundamental information that we have about his work history. There's nothing about this work history which is particularly different from many, many other electricians I've interviewed over the past 20 years who've worked in substations or in municipal distributing facilities.

I've seen people who've worked in Denver and in Colorado Springs and in Fort Collins and most of the cities in Western Nebraska and Eastern Colorado and many railroad substation electrical employees and so on. They all have about the same history. So I believe that those are the most important items.

Now, I understand that there are transformer analyses, but I don't know what dates they're from, so I can't give you any way of distributing those over the years in which he worked with those materials.

Q Do you know from any source what concentrations of PCBs were contained in any of the transformers on which he worked?

A I don't have those documents. I understand there are such documents; I have not seen them. Typically, in my experience, transformers which were listed as non-PCB transformers throughout this last 20 [32] years had

concentrations from anywhere above 50 parts per million to something under 1 percent, maybe 5,000 to 8,000 parts per million at the maximum.

Q. And is that something you're assuming for purposes of your opinion?

A Well, it's fairly typical of the era. I think it's reasonable to assume that that's so, yes.

Q All right. Do you know how long Mr. Joiner was exposed to mineral oil contaminated with PCBs, how many years?

A Well, he began to work in 1973, and he says he thinks he stopped sometime around 1987.

Q So you would be assuming a 14-year exposure?

A That's what he believes he was exposed—that's the period that he says. He says he does not know what the situation was after that.

Q In reaching your opinion, though, what length of time are you assuming?

A Well, that's the assumption that I have, because I have no history of his having worked with these materials before 1973. His medical history prior to that indicates that he worked—did a little farming, some farm chores early, and worked as a delivery boy and stocker—let me get the exact—baled hay and picked watermelon while he was in high [33] school up to 1972, and then in 1973 he began to work for the public utility.

Q Now, during the years that Mr. Joiner may have been exposed to mineral oil contaminated with PCBs, how often, if you know, was he exposed?

A I don't have, and have not seen that anyone has collected, the transformer records for who worked on them. I don't know how this utility works as far as its record maintenance is concerned, but other utilities that I've looked at keep a log for every transformer, and actually one could set up a record of how many he worked on, but how many hours it took him to do each job, it would be difficult to say. But from his descriptions to me, it was a very frequent activity.

* * * *

Q On the order of daily?

A I would say several times a week, not necessarily daily. It's more likely that there were periods that were quite intensive and went on for a number of days when he was working on a large transformer and baking it out, something of that sort, than that it was every day. So I think it was episodic but not every day.

Q Have you been shown any documents that would reflect the presence of dibenzofurans, dibenzodioxins, [34] or chlorinated benzene in any of the mineral oil on which Mr. Joiner worked on or around?

A I don't have any documents which would answer that question, There are, so far as I can tell, no quantitative analyses that have been supplied to me that answer how much and when.

* * * *

Q Or if any; is that correct?

A I don't have any documents at all. I think that one simply has to look at the likely chemistry of the situation and what's known about PCBs manufactured in this period and assume that there was some furan present, that there may have been some dioxin present, depending on the particular fire and circumstance. There probably was some chlorinated benzene since that's almost always a contaminant.

Q But that's speculation on your part in this case, is it not?

A No, it's not speculation. It's a reasonable assumption based upon what we know about the era. I cannot tell you what the specific concentrations are at any place or time. I mean, I think that could be answered by going to the supplier of the oil and getting their internal documents for the quality assurance on the materials, but I don't have such material.

* * * *

[37] Q Do you know when Mr. Joiner started smoking cigarettes?

A Well, I know what he says and what is recorded in the various medical records; there is some discrepancy among them. Around age 19. In the history which he completed for me, he said about 19 years was when he began to smoke cigarettes.

Q At age 19 or he smoked for 19 years?

A No, no. He says he—the question is, "How old were you when you began to smoke?" He says, "About 19 years."

Q All right. Does he indicate when he stopped smoking?

A Yes. It says, "How old were you when you [38] stopped smoking cigarettes regularly?" The answer is, "28 years," so I make that to be about nine years of cigarette smoking.

Q Did he indicate how many cigarettes he would smoke?

A Okay. The question I asked him was, "What was the usual number of cigarettes you smoked per day? Please give best estimate." And he said, "One pack per 24 hours."

* * * *

[39] Q Did you find any reference that he had smoked up to two packs a day for 15 years?

A I think I saw that somewhere.

Q Would that be 30 pack years?

A It would be, but that seems completely inconsistent with what everyone else found.

Q Do you know if that history was given by Mr. Joiner before he retained Mr. Warshauer?

A I really couldn't say. I don't know.

* * * *

[44] Q I want to make sure I've covered your second opinion. Have you, as far as you know, given us all of the facts on which you base that second opinion, that Mr. Joiner for many years had exposure to various mineral oils contaminated with PCBs?

A Well, I haven't talked at all about how he worked and the conditions under which he worked, all of which contributed to that.

Q All right. Tell me what facts you rely upon there.

A Well, for the first, at least, 12 to 13 years of his work he had no protective gear. He worked with [45] and in the oil on a regular basis. He describes frequently having his skin doused with oil. He describes needing a new pair of shoes every six months because of the oil destroying his shoes. He describes being inside the larger transformers on many occasions and being covered with oil. He describes inhaling the smoke on a number of occasions from baking out transformers.

He describes his desk as being in the area where the transformers were actually being serviced, so that—and his tools being constantly covered with oil. Again, this is very typical. Every electrician that I've ever talked to from this era told me that they used to use the oil from the transformers to oil their tools to prevent rust and to keep them in good shape. So he has multiple exposures by dermal and respiratory route.

Q Now, do you know how often, if at all, the mineral oil was contaminated with PCBs?

A No, I don't know that. As I said, I understand that there are documents, but I don't know from what era.

Q All right.

A I would say that from the era that we're talking about, virtually all of the mineral oil would [46] have been contaminated within the ranges that we're talking about. I think it would be unusual for it not to be contaminated at that time.

Q All right. So for purposes of your rendering your opinion, are you assuming that virtually all the mineral oil was contaminated with PCBs?

A Yes.

Q Okay.

A With concentrations between 50 and a few thousand parts per million during this era of time.

Q And that would be up to 1 percent?

A Up to 1 percent, yes. Generally speaking, I would say that in my experience the maximums have been around 6,000 parts per million, but as many have been 50 to 200 as have been 6,000.

Q And that's what you're assuming?

A. Yes.

Q Now, are there any other facts that you're relying on in rendering that second opinion concerning the many years that he would have been exposed to mineral oils contaminated with PCBs?

A I don't think I have any other information that would be helpful.

Q All right. Now, let's turn to the third opinion which was that—and I'm paraphrasing, so if [47] you want to go back—if I misphrase this, feel free to correct me, but as I understood it, your opinion is something like the lung cancer was caused by or contributed to in a significant degree by the materials with which he worked.

A Good notes.

Q All right. Now, tell me the facts on which you relied in reaching that opinion.

A Well, it's my opinion that cancer is a multifactorial disease. As a consequence of this multifactorial pattern of causation, various individuals respond with malignant disease at some time in their lives, and it is unusual for a single cause to be identifiable.

In my analysis of the information available concerning Mr. Joiner, I find three interesting factors. The first interesting factor is that there is at least one case of lung cancer in a first-order relative. There is not much evidence that sporadic cases of lung cancer have a familial pattern. There are recently some interesting studies on families of lung cancers, but they're pretty unusual. But there is at least one case in a smoker in his family. That's the first interesting thing.

The second interesting thing is that we do [48] know that Mr. Joiner smoked for a relatively significant period

of his life, but from the point of view of causation of lung cancer, a very—a low-end dose and early, and he stopped 12 years approximately before he got sick. But if the most recent studies on smoking and cancer are correct, our previous assumptions that as time passed the risk would disappear may have been unduly optimistic. So we have some risk of lung cancer because he was a smoker; however, the likelihood of his developing lung cancer at age 37 on a statistical basis is extremely small.

If you compare the lung cancer rates at age 60, which are around 400 per 100,000 person years, with the lung cancer rates in the 30s, which are almost too low to detect, somewhere around 10 to 15 per 100,000 and most of those in the later 30s rather than the early 30s, it's pretty—pretty low risk, but it's there.

The third thing is that we have a period of approximately 15 years of exposure to a material which, in and of itself, is an animal carcinogen, likely contaminated with additional materials which are animal carcinogens, carried in a vehicle which is a known carcinogen, and other work which he did which had some potential carcinogen exposure. It's not quite so clear, but he talks about using mineral oil as a—using [49] mineral spirits as a cleaning solvent.

So I see his occupational exposure to the materials containing—to mineral oil containing PCBs as a significant portion of his history. I am a firm believer in the concept that if there is more carcinogen exposure, there is more risk of cancer and more cancer in fact, and I believe that in that fashion, at least these three issues, some perhaps genetic predisposition, not well characterized, about which we know very little; smoking, about which we know more; and an occupational carcinogenic exposure to a material known to be an animal carcinogen and quite strongly suspected by most people being a human carcinogen as well, I think that those elements together are a significant portion of the causation of this disease.

Q Now, which of these substances is the known animal carcinogen?

A Well, I think that there's very little question that PCB is. There's sufficient information on PCBs. I brought the IPCS World Health Organization criterion because it's just hot off the press, and the summary which appears on page—let me find it—478 indicates that as of 1987, IARC had concluded that the evidence for carcinogenicity in laboratory animals is sufficient. This is the latest piece of information, [50] and there is no reason to doubt that, and they also concluded that PCBs are probably carcinogenic for humans.

Q Is it your opinion that Mr. Joiner's lung cancer was initiated by his cigarette smoking?

A I don't have an opinion about that. That would be purely speculative. It could have been. It could have been initiated by something entirely other than that. I think what's clear is that when you stop smoking, the promotional effect goes away, at least the nongenotoxic promotional effect.

Q The promotional effect of what?

A Of the cigarette smoking.

Q Is cigarete smoking a complete carcinogen?

A Hard to answer the question. I think there are components in cigarette smoke that have the potential for being complete carcinogens. For example, ethylene oxide is present. I think ethylene oxide can be both a promoter and an initiator. On the other hand, there are—and there are anthracenes and various polynuclear aromatics, all of which appear to have the capacity to be complete carcinogens.

On the other hand, there are a lot of materials which are only initiators, like urethane which is in cigarette smoke, or the tars which are probably [51] purely promoters. If you go back to the earliest research in cancer, the Rouses' work on chicken papilloma, the promoter used in those was tar, coal tar in that case but not terribly different from cigarette tar.

Q Let me ask you with respect to your opinion, in addition to cigarette smoke, mineral oil—well, let me start over.

In addition to the cigarette smoke and the PCBs, in your opinion, what other various chemicals were present in Mr. Joiner's workplace that you include in your opinion of—

A Well, I told you that there's mineral spirits. Mineral spirits is a very large kind of diffuse category of materials ranging from substances with flash points around 90 to substances with flash points of 150 to 200. If there —coal tar-derived mineral spirits, which there certainly are and they're still on the market in the United States, some of those may have had benzopyrene and other PNAHs in them. I think I would put mineral spirits in the mix as being a potential promoter and perhaps even an initiator.

Q Of Mr. Joiner's cancer?

A Yes. I think that—on the theory that cancer is multifactorial and is the result of all of [52] these influences working together in the right sequence at the right time, that's something that he did tell me about that I would add into the mix.

Q All right. Relative to mineral oil contaminated with PCBs, do you know whether Mr. Joiner was exposed to more mineral spirits or more mineral oil contaminated with PCBs?

A Oh, much more mineral oil—of the oil, much more.

Q What do you base that on?

A Because he said he occasionally used mineral spirits, and he was almost reg- —and he was regularly exposed to mineral oil. And the quantities were just enormously different. I mean, you're talking about a transformer that might have a couple hundred gallons of mineral oil in it and the use of a few gallons on a rare occasion of mineral spirits.

Q All right. Now, let me ask my question again. Relative to mineral oil contaminated with PCBs, do you know whether Mr. Joiner was exposed to more mineral spirits or mineral oil contaminated with PCBs?

A I think more mineral oil contaminated with PCBs—

Q And what—

A —by far.

[53] Q What do you base that opinion on?

A The history as he gives it to me and his deposition. I think you could answer that by looking at purchase records. I don't think that's a very obscure question, but I don't have those records.

Q Do you recall whether Mr. Joiner, each time they used a foot tub to move mineral oil, that they cleaned it with mineral spirits, each and every time?

A He didn't say each and every time. He said on some occasions. Sounds to me like they often didn't clean the tubs. It depends on whether they were using the tub to collect used oil that was going out, or if they were going to reclaim that oil, in which case they did try to clean it.

Q Okay. With respect to the filtering system that they used, did he tell you that they cleaned it with mineral spirits?

A On occasion.

Q And so you're assuming that he did not clean it each time.

A That's correct.

Q And you're assuming that they did not clean the foot tubs each time.

A Yes, and that seems to me to be consistent with his discussion.

* * * *

[54] Q Dr. Teitelbaum, let me ask you this: In taking the medical history from Mr. Joiner, did you make any determination about his exposure to secondhand cigarette smoke as a child?

A Yes.

Q And what did you determine there?

A Well, I determined—it's, I think, repeated in several things. His mother was a smoker at least, and he was certainly exposed to secondhand cigarette smoke as a child. What that amounts to is a debatable issue, but I would concede that he was exposed.

Q Do you know whether his father also smoked?

A I believe he did, but . . .

Q Do you know how much his mother and father smoked?

A No, I don't have that information, as I recall.

* * * *

[55] What significance to your opinions does it make that both his—if you assume both his mother and father smoked and were characterized as heavy smokers all during Mr. Joiner's childhood?

A Well, I don't know what to make of that. I mean, I have followed the EPA and the general scientific debate on sidestream smoke, and I think that the evidence is building that sidestream smoke probably is carcinogenic.

At the same time, I think that the dose of sidestream smoke is probably extremely small, and what's in that sidestream smoke is not at all clear, and it's probably changed over time depending on what tobacco was being burned, what paper was there, and so on. I would say it's part of the mix.

Q When you say "part of the mix," what do you mean?

A I explained to you how I think cancer arose in Mr. Joiner, and I think that his total life experience would be part of that. And the fact that his parents smoked would be part of that, but I would have no way of evaluating it and looking at the very large studies that [56] have been done. The risk for sidestream cancer—sidestream smoke-induced cancer is quite low. It's real, but it's very low.

* * * *

Q All right. In taking the family history from Mr. Joiner, did you determine whether any of his other relatives had been diagnosed with any forms of cancer?

A Let me go back and look at that because I don't want to speak out of turn. I think there was some discussion about one uncle who may have died of cancer.

Q Did you find any reference in the medical records to relatives other than his mother who had contracted some form of cancer?

A I believe so.

Q And what was in the medical records?

A Just hang on while I take a look a moment, try to tell you the answer. The 1990 record—1991 records from Dr. Morley indicated that his mother died of lung [57] cancer, two uncles died of unknown cancer, and various members have heart disease. The Archibold Hospital records from 5/92 show no family history of cancer, but other records agree with Dr. Morley's records.

Q All right. What significance is it to your opinion that, in addition to his mother, that one of his uncles had lung cancer and another uncle had some form of cancer which at this point is unknown?

A Nothing more than what I've said already.

* * * *

Q Well, let me ask you this: Turning to the exposure to his skin, do you know the amount of skin area that would have actually been exposed to mineral oil contaminated with PCBs?

A At various times I would say he was covered from head to foot, from his description. I think in general my discussions with many electricians, including [58] Mr. Joiner, is that the usual exposure is feet up to about the midcalf and arms up to the shoulders, because they would frequently work under the surface of the oil to make minor connections and corrections in the transformers. That would be pretty typical.

Q Do you know what the absorption rate through the skin is of PCBs that are contained in contaminated mineral oil?

A Well, I tried to answer that question. I can't find any data that anybody's studied that.

* * * *

[61] Q All right. In addition to mineral spirits, cigarette smoke, and PCBs, were there any other chemicals in Mr. Joiner's workplace that contribute to your opinion?

A In the occupational/environmental history which I took from him, he listed oil and paints as the only other two materials, the oil being something apparently other than the PCB oil, and the paints being apparently an occasional exposure. And I would think that the paints, if they're a problem, are a problem because they contain mineral spirits in some instances. That's all he indicated he worked with, so that's all I would point to. I don't have anything else.

* * * *

[65] Q All right. You've identified oil, you've identified paint, you've identified mineral spirits, you've identified PCBs. Is there any other chemical that was present in Mr. Joiner's workplace that you believe contributed to his lung cancer?

A Not according to anything he told me. I don't know of any other chemicals that were present, period. That's all we have.

* * * *

[67] Q Now, in reaching your opinion, did you assume that Mr. Joiner had any particular body burden of PCBs?

A Do you mean did I assume some quantity, no.

Q Why not?

[68] A Because I don't think that there is any way of relating the quantity of PCBs measured in anything with any outcome. All you can say is if you have more, you're more likely to have disease, and even that is not quite so clear when you begin to look at the studies.

Q Do you know what Mr. Joiner's body burden was as tested by the Triangle Laboratories?

A I've heard the numbers. I have no comment to make about it. I haven't seen—I know Triangle Laboratories well. They had their ups and downs over the years. With each specimen they provide a very extensive quality-assurance document. I have not seen that, and if I do see it, then I'd be able to make some evaluations as to whether I think the number is relevant or not relevant.

The number which was measured, as I recall, was about .5, but I don't know what to do with that because I don't know about the analysis that was done, and I don't know when it was done in relation to their other problems, whether it was before or after they were certified and so on. There are lots of things in that.

Q Do you know what the general background levels for PCBs and adipose tissue were in December of 1991?

A Where? And—

Q In the southeastern United States.

[69] A —by what method, and are you talking about total PCBs?

Q Yes, total PCBs for the southeastern United States.

A Okay. I'll allow—

Q Adipose tissue samples.

A I'll allow that in my mind when you talk about background, you're not talking about a normal level because a normal level would be zero. But the background, because of general environmental contamination, maybe is around .5 in fact, maybe. And I say maybe because there isn't a single definitive study that would answer that. They attempt to answer the question through what's called the National Human Adipose Tissue Study, NHATS. Really hasn't answered it.

The only year that's been studied is 1983, and it was kind of a trial balloon, and the data came out and was critiqued in many different ways and really is not to be considered reliable. So I don't know of any good study

that would answer that, but by impression from reading all of the studies which are around suggests it's around .5. But whether in Thomasville or Jacksonville or Fort Walton Beach they're the same or different from that, I don't know.

* * * *

[70] Q Can you say to a reasonable degree of medical probability whether Mr. Joiner's body burden of PCBs was higher than background nonoccupational levels before his diagnosis in August of '91?

A I have no opinion about that. It would be pure speculation.

Q Why would it be pure speculation?

A Because you don't have a measurement from before; you don't have any way of comparing it to the general population; you don't have anything that you could base that on. It would be absolutely a guess. The paper that's quoted in HSDB says that in their opinion, and it comes from—again, from a series of papers quoted in the EPA Drinking Water Criteria, that the burden of PCBs in human fat has been found to range between 500 and 1500 parts per billion.

Q Which would be .5 to 1.5 parts per million?

A That's right.

Q And that would be in adipose tissue?

A That's what it says, and that's from a paper [71] —that's from the U.S. EPA Drinking Water Criteria. On the other hand, in Michigan it's different, as you know, because of the PBB and PCB contamination from the Great Lakes. There's all kinds of numbers.

* * * *

[73] Q So you don't have any quantitative data to assess either exposure or dose here.

A That's correct. I would not have any way to do it. I don't have a reliable measure of PCBs in his body before he became ill. I don't have any reliable information concerning the contamination. I only know that in

the era we are talking about, the typical [74] materials were contaminated, as I've previously discussed, and he worked with it over a long period of time, and material is absorbed through the skin. That's as far as we can go.

* * * *

[75] Q Let me ask you this: Do you know the minimum temperature necessary to create furans or dioxins from the arcing pyrolysis or combustion of PCBs?

A You know, you asked that question of Dr. Schecter, and I thought it was—or whoever asked it, and I thought it was a very interesting question, and I tried to answer it. I didn't have at hand the kinds of chemistry and physics textbooks that would answer it. I don't know the answer to that, but it seems to me that that's a pure physical chemistry experiment, and that should be something pretty easy to answer in the laboratory.

I think we know the answer to that for, say, phosgene, its around 200 degrees C, and to create a more complex structure, it's probably somewhat higher than that. But I can't answer it now, and I didn't—I [76] couldn't get into the physical chemistry literature to get an answer to it, but it's an interesting question.

Q Mr. Warshauer didn't give you any of the analytical chemistry studies that have looked into that?

A Mr. Warshauer gave me what you have in front of you, and I think that he probably thought that was outside the scope of my expertise, as I would ordinarily think it is. But the question was interesting and I thought it worth looking up, but I couldn't answer it.

Q From the history that you obtained from Mr. Joiner or from any other source, were you able to determine the temperature created from the stadium lights that were used to bake the transformer coils?

A He says it was enough for it to smoke, and oil smokes at around 700 degrees, 800 degrees approximately.

Q Fahrenheit or contigrade?

A Centigrade. You'll get smoking at that.

Q Smoking of what, the mineral oil?

A Well, of the mineral oil or what's in the mineral oil. You'll get steam below that because there's water in it, but he describes it as real smoke, and I would say we're probably up around 700 degrees C.

Q And was that your assumption when reaching your opinion?

A About what?

[77] Q Is it relevant to your opinion, the temperature?

A It's relevant that when he heated the material, the more volatile substances would come off. It's not terribly relevant as to whether or not he was exposed. I think that the question you're asking is one that a physical chemist needs to answer, and I really can't—he describes it as being hot enough to smoke, and I think that's a sufficient piece of information for me.

Q You don't purport to be a physical chemist—

A Heavens, no.

Q —or an analytical chemist?

A No. I took physical chemistry and survived. I'm happy.

Q What kind of lung cancer does Mr. Joiner—did he have?

A Well, it's described as a small cell. But, again, that's a problem because he didn't have a total lung resection, and if you look at the cell type analyses that have been done in sophisticated studies, usually what you're hearing is a predominant cell, but if you do a large enough sampling, you'll find that there are more just the single type present.

* * * *

[78] Q Let's turn now to the literature, your bibliography.

A Okay.

Q I notice that you have some studies in there done by Lucy Anderson.

A Yes, hot off the press.

Q How many studies did she do that you have been able to identify?

A Well, I have, I think, four that I've looked at. I'm not sure they're all separate studies. I think they're interim reports on the same study or on the steps in the development of that study. The first [79] publication—let's see if I can—if I've got them right. I think the first publication that she put out was in 1983, and then in 1986 she did the single-dose study, and then in 1991/92 she published the promotion study with polynuclear aromatics, and then the 1993 publication is the single-dose study on infant mice on selective congeners. So I think what you're looking at is an ongoing work.

Q Was the promotion of lung cancer in the Lucy Anderson studies only for infant mice?

A I'll have to look and see. Was it "only" as distinct from any other kind of mice, or is that the only thing that she studied? What is it that you're asking me?

A Okay. I think I can answer your question.

Q Go ahead and answer the question.

A It appears to me that all that she studied were infant mice in the most recent publication, so that's as far as we can go. Whether the same thing would be present in other animals, I can't conclude from her study because she didn't give any information about [80] that.

Q Do you know if in the Lucy Anderson studies there was only one dose at which lung cancer was promoted?

A I'm not sure that her study answers that question. I think that that's—what you're asking is, is that the only dose at which, within the parameters of the experiment, she noticed that? I would say yes.

Q Okay.

A But whether the answer to your question on an absolute basis is that's the only dose at which it was promoted, I wouldn't be prepared to say that because she did not sacrifice over a period of time to answer that question.

Q Okay. Do you know of any other studies that you have located where somebody other than Lucy Anderson studied the promotion of cancer in animals by the administration of PCBs? Other than Lucy Anderson, anybody else, any other study that you found.

A A pure promotion study?

Q Yes, sir.

A Well, I can't say that I know all the studies, but I've read a lot. Most of them would not be sufficiently narrow to say that they studied a pure [81] promotional effect, so I don't think I can give you a study where the design of the study was to look at promotional events in whole animals.

I mean, you have all kinds of studies on the—on binding at the ah locus and so on, all of which contribute to the knowledge about promotion, but I don't think that there's another whole animal study which would—or another group that's doing whole animal studies that would answer that, at least that I've seen.

* * * *

[84] Q Well, if a chemical as a general matter is characterized as a promoter of cancer in humans, do you [85] classify it as a human carcinogen?

A It might be, but it is a chemical which participates in the generation of cancer. See, this is really a—it's a failure of the current terminology because our regulatory system and the scientific knowledge are not necessarily concordant. You surely don't want to go around exposing people to promoters.

Q Is that because they have a—as a general matter they would have a carcinogenic potential?

A No, it's because they would cause more cancer, but not because in and of themselves they're carcinogenic. And I think we're playing with words here. I think it's like saying if you need a detonator and dynamite together to get an explosion, is the detonator considered an explosive? And it may be for the Alcohol, Tobacco, and

Firearms Division, and you maybe would get charged with possession of explosives if all you had was the detonator in your hand, but that isn't going to blow up.

* * * . *

[87] Q Other than the studies by Lucy Anderson, do you know of any other animal study where lung cancer was promoted in a species other than mice?

A I don't think anybody's studied any other study. I think that now that the 1993 Anderson publication came out, I suspect you're going to see some more studies on that because now there seems to be a clean model that can be looked at.

[88] Q Is biologic plausibility a fundamental principle of toxicology?

A Yes.

Q All right.

A Well, no, wait. It's not a fundamental principle of toxicology, it's a fundamental principle of epidemiology, and it comes from Bradford Hill's criteria, and it is a fundamental principle which attempts to assess inference of causality based on scientific study.

Q Is it sufficient to establish biological plausibility to find carcinogenesis in only one animal species?

A It's a pretty good start. I mean, I think it is—

Q Is it sufficient?

A I think it's sufficient when you have all of the other information you have about PCBs as carcinogens. It's perhaps not sufficient to establish that a particular kind of cancer would occur in all animal species, but it certainly is much more consistent with the total body [sic] than if she had not found it.

If you came to me and you said, "Dr. Anderson has done this study and it's negative. Is that consistent?" I would say, "No, that's not consistent. [89] That's perhaps revolutionary." In fact, I would think that if you studied any kind of cancer well, you would find that it's probably—that PCBs are probably capable of promoting that cancer in a particular study design.

MR. COCHRAN: All right. Would you read that answer back to me, please, ma'am?

(The preceding answer was read by the reporter.)

THE WITNESS: Body of knowledge, I think, is what I said.

* * * *

Q Now, turning to your bibliography, I think we identified as Exhibit—is it 12A?

A Yes, right.

Q All right. What, if any, epidemiological studies have you reviewed in reaching your opinion?

A Well, I think I've reviewed all of those that are around on PCBs. I think that the study which in the long run will give us the most information is probably Bertazzi's group. I just saw Professor Bertazzi in Nice and I asked him if he has anything new coming out, and he says yes, he has something new coming out, but he wouldn't tell me what it was, so I don't know what it [90] is. Apparently, they've done some further study of this group of capacitor workers.

He could have another five years of observation, which would be a lot of person years. I think that's the best study. You've got Kuratsane's studies from Japan. You've got a few cases of lung cancer there. They're not very convincing, as the Japanese lifestyle is different. There's—it's, again, suggestive but not convincing.

I think that the recent review by IARC of all of the studies, including Gustavsson, who was also at the meeting, and Hogstedt, who was also there, and—all of whom talked about this, I think everybody is willing now to take the position that PCBs are human carcinogens, but I don't think that they would—any of them would be willing to say that they have evidence, convincing evidence, that PCBs cause any single kind of cancer.

I think they would say that they are human carcinogens and that the evidence now is that they can promote a whole series of cancers: hematologic, kidney cancer, certainly lung cancer is on the list. They've been observed

and they appear to be out—by Bertazzi's work, well out of proportion to what would be expected.

Q Okay. You said you have reviewed all of the [91] epidemiologic studies. Are there others that you have reviewed that are not on that list?

A These primarily were the ones that dealt with—that mentioned lung cancer and so on. Yes, there's a whole series of them listed in that WHO document, and I've—whenever one comes out, I collect it and I read it.

Q Do all of the epidemiological studies show the same thing; that is, are they consistent?

A No, but—all do not, but there is certainly general agreement that for groups which have been studied long enough and for which the exposure is well enough characized, there is an increased risk of cancer in humans. But you have a very varied group. You have groups where you have mostly women exposed; you have groups where you have mostly men.

Most of the studies come from capacitor workers, not from people who did this kind of—the work that Mr. Joiner has done. I don't know of a study in industrial electricians. Be interesting to do, but I don't know of such a study. And probably it would be one you could do because a lot of these people belong to the unions and would be fairly easy to identify.

Q Did the Bertazzi study have a very short follow-up period?

[92] A Yes, that's why I said he—he published it in '87, and I think he wrote it about—sometime in '86. We could theoretically have another five or seven years of follow-up, and he says he has something in the works, but wouldn't tell me anything about it.

Q If an epidemiologically [*sic*] study has a short follow-up period, does that put a limitation on the interpretation of the results?

A Can put a lot of limitations. If you're dealing with something which is very highly penetrant, a disease which occurs quickly and very often, like if you study leukemia in radiation victims, and you've got five years of follow-up,

it's clear in five years that you're going to have an increase in leukemia in people exposed to radiation.

On the other hand, where you're dealing with something which is a relatively weak carcinogen and a relatively rare disease—I mean, if you wanted to study PCBs in electricians at age 35, I haven't done the calculations, but you'd need millions, I think, millions of exposed people to get a statistically significant finding, or millions of person years anyway.

Q What was the size of the cohort that Dr. Bertazzi studied?

A I think 1500 approximately. Mostly women, I [93] don't remember, or half women, half men. I'd have to look back.

Q So would that, again, having a small cohort, be a limitation on his results?

A Got to wait longer.

Q Well, in addition to waiting longer—I mean, I take it you're saying you have to wait longer because you have such a small cohort?

A Well, you need a number of person years of exposure and a number of person years of follow-up. You can get the number of person years of follow-up by having a big group for a short time or a small group for a long period of time. A thousand person years of follow-up standardized over, they may give you an answer comparing studies, but—

Q Then would the study be inconclusive due to low statistical power?

A That's one of the accusations that have been made, and he himself says that they—you know, that the lung cancer occurrence was tending or trending towards statistically significant, but was not statistically significant.

That doesn't really mean anything, as you well know, because statistical significance is not the only criterion for interpreting information. It suggests [94] that there may be an error in the study, but if it's biologically plausible and it's consistent with other studies, even though it

doesn't reach statistical significance, you'd best be very, very cautious in saying the effect isn't there.

Q Did Dr. Bertazzi correct for confounding factors like smoking?

A He didn't because he didn't have that data. He may have that data now.

Q He did not?

A He did not, no. But he had a lot of women, and women are not big smokers apparently, he says, in Italy.

Q Was there a confounding factor involving the local rate of incidence?

A Well, there was a problem—there's the issue of whether he should have used local—a local comparison group or a national comparison group. I think the best of the two is really neither. I think you have a real problem with how you do that because, you see, if you choose the local comparison group to calculate your standard mortality ratios, the people who died locally already include in the denominator all the people who may be included in this study, okay? Everybody who died of lung cancer is going to be [95] included in the denominator, and it's going to include the people who were exposed here. So you're going to need a larger group in the numerator in order to reach statistical significance. So he said, "Okay, I'm going to go in the national levels."

Well, in the national level, you don't know how many of those people were exposed to PCB either. There's a paper by Alan Feinstein—Alvin Feinstein called "Fraud and Deceit in Epidemiologic Studies" in which he talks about inadvertent fraud based on death certificate studies, and he deals with all of this issue. And he says that the time has come to stop using death certificates because you have this kind of fallacy built into the study, and it tends to move the study towards the null and eliminate statistical significance.

That's why I said previously that the simple fact that it did not reach statistical significance isn't enough to convince me the study is not right.

Q All right. Let me ask you: Based upon the epidemiologic studies that you've seen, is there a finding of a significantly increased incidence of cancers of a general type in an exposed population when compared to an unexposed population in a carefully documented epidemiologic study?

A I think that's a subject for a doctoral paper, [96] and I'm going to say it's too vague for me to answer. You're going to have to tell me what you mean. Are we talking about all cancers? Are we talking about general populations? I think that the question you're asking me now has been answered by the expert commitee that IARC had together, and their conclusion was there's enough evidence to say that it's probably a human carcinogen, there is not enough evidence to say that is proved, and I think I would have no problem accepting that.

Q And when you say that it's a human carcinogen, you're just talking about generally without respect to any particular—

A That it's capable of causing cancer in humans, without saying which cancers it's capable of causing. I do not believe that there's any good evidence that PCBs in any specie have a signal lesion. I mean, we have a whole series of cancers which have been observed as increased: kidney cancer, lung cancer, hematopoietic cancers. I've even seen one study on prostate cancer. Lots of opportunities.

* * * *

[101] Q All right. As far as you know, does this Defendant's Exhibit 7 contain an accurate listing of the cases in which you've testified either at trial, deposition, or hearing from approximately May of 1983 through approximately January of 1992?

A I can't say how accurate it is. It's the best list that we could put together at the time, and since we no longer maintain it and I don't have anything to document this and can't reach it before 1988, I can't [102] tell you how accurate it is. After 1988, it's pretty good.

Q All right. And you say "we," when you say "we prepared it," are you talking about the folks in your office?

A Well, I was at Denver Clinic at the time it was originally prepared, and it was prepared by somebody at the clinic based on the records that they had. But I don't have access to them; they've gone bankrupt. I have no way of confirming anything before '88.

Q All right. But with respect to after 1988, it appears to be fairly accurate.

A Reasonably accurate. We got asked for it often enough so that we just made a list, and we add to it as something happens.

Q All right. And so you've reviewed this from time to time, then.

A Yes, roughly.

Q All right. Now, do you know how many times you testified in calendar year 1990?

A I don't know. Whatever's here is what there is. You can count them as well as I can.

Q Would 57 be a correct—

A Whatever it is, it is. That's how we made the list.

[103] Q All right. Since 1991—excuse me, since 1990, have you continued to testify with the same frequency that you testified in calendar year 1990?

A Well, you've got the list here through 1992, and so whatever there is here is what I've done. Actually 1990, I think, was probably a year in which I had more appearances, but most of them were very small issues, and I think that there have been less issues that I've testified on since that time. But probably 30 to 40 times per year would be a reasonable guess.

* * * *

Q Okay. You indicated we had it through calendar year 1992. Actually, if you look at the list, it only goes through January 14th of 1992, doesn't it?

A Oh, I don't know, whatever you have. I mean, I'm surprised you don't have more. Mr. Freeman's firm

should have a more recent one than that because they took my deposition in a case and asked for this. Ask Mr. Parnell, he probably has it.

* * * *

[104] Q Let me ask you, looking at these numerous cases here that you testified in in calendar year 1991, in how many of those cases, going down that list, did you testify for the plaintiff?

[105] A I haven't counted for that year, but it's almost always, I would say, for the plaintiff. Let's see for '91. In '91 I appeared for Eli Lilly as the defendant in Wyatt-Jose, and in—I think that was the only defense case I appeared in that year. That's no reflection of what work I do; that's only what cases actually went to some deposition or—

Q Well, let's—

A —trial.

Q —look at the 57 cases in 1990. How many of those, looking at the list, did you testify for a defendant?

A No, please, it's not 57 cases, it's 57 appearances, and sometimes it's repeated appearances in the same case. But I haven't looked at this one, so I don't know. I haven't seen this list in a long time.

Morrison versus Eli Lilly, I appeared for Eli Lilly. Sorrells, I appeared for Merck. Mullens, appeared for Wyeth. I think that's all.

Q So of the 57 appearances in 1993, three were for defendants?

A Three for defendants, that's correct. Usually I see the people who are sick, and usually if I feel that the causation is what I think it is and I write that in a report and somebody comes to me and says, [106] "Will you testify about that?" I will say yes. If I've told it to the patient, I'll tell it to the Court as well.

* * * *

Q Now, how much time each year do you spend in the United States?

A About nine months.

Q So these appearances that you have would take place during the remaining nine months of the year.

A Right.

Q So how often do you testify?

A By deposition?

Q Or court appearance or at a hearing.

A In court, not more than three or four times a year, maybe five times a year maximum, some years not at all. I think in '90—was it '91 or '90, there wasn't a single court appearance. By deposition, perhaps three or four times a month.

Q All right. And what do you charge?

A Depends. You have my correspondence file; it's got all the fees laid out. The current fee is $4,000 a day, $2500 for a half day, $500 per hour.

Q When you came to Atlanta to examine Mr. Joiner [107] back in July, how much did that cost?

A Half day, I believe. I was there for something else and saw him in the morning. I charged him for half a day.

Q $2500?

A Right.

Q And for your appearance today, it's another $4,000?

A That's correct.

Q Now, how long have you charged those rates, $4,000 for a full day and $2500 for a half day?

A About 1989, something like that.

Q So if you had 57 appearances in 1990 at $4,000 each—

A No, that's not correct. You're making an assumption.

Q All right. What would it have been?

A I have no idea, because many of them are an hour. I mean, you look at a Worker's Compensation case, and in Colorado we don't try it on paper as you do in many states. You have to give a deposition or appear at a hearing and those take an hour, they don't take a day or a half a day, so I have no way of knowing.

If you want to know what my total income is in a particular year, I can't give you that, but I can give [108] you an estimate. And you have to remember that I have 16 employees, so we're not talking about just one person's money in the pocket.

Having said that, I can't answer your question because I don't know for 1990, but I can give you a general idea of what my income is if that's what you want to know.

Q All right. What is your income annually simply from testifying?

A Well, I don't get paid that way. I get a salary like anybody else gets a salary. I have a corporation and a lot of employees and a building and very high overhead, and I get paid a salary like anybody else does.

Q What's your salary?

A I get—my after-tax monthly salary is $11,000.

Q What percentage of your income is attributable to involvement in litigation?

A I can't answer that either. I can tell you that 70 percent of my income comes from my consulting and 30 percent comes from patient care, although my time is 60/40.

Q All right. When you say consulting, is that consulting with attorneys who are involved in [109] litigation?

A It's everything I do in consulting. I consult with companies, I consult with attorneys, I consult with government agencies. Anything that I do on a case that's—anything other than—other than patient care or teaching would be included in that.

* * * *

[110] Q Now to be specific to this case, is there any study that you know of anywhere in humans that indicate that small-cell, being specific to this diagnosis, lung cancer was caused by PCBs?

A No. It's an impossible research question to investigate, I think, in the first place, and in the second place, there is no such study.

Q I see.

A So I think it's—in other words, I think one exists at the present time.

[111] Q I see. The same question with respect to PCBs as contributing to small-cell lung cancer in humans.

A That, I think, could be done, but has not been done.

Q It has not been done; is that correct?

A That's correct.

Q And there is no study of small-cell lung cancer that indicates that it was promoted in humans, is there?

A No, there is no such study. But let me comment on the fact that if you ask about small-cell cancer because of Mr. Joiner's diagnosis, I have pointed out that we do not have more than a limited sample, and that at the very first question which Mr. Cochran asked me, I pointed out that I am satisfied that to the best of the ability of the physicians who were treating him to say today that's what his diagnosis is, but I would not accept that that is, in fact, what his diagnosis is in the absence of a better tissue diagnosis.

Q Now, can you point to any study in animals where the person conducting the study has suggested that the animal developed small-cell lung cancer?

A I don't think there's an analogy in animals that would be relevant, so I can't point to such a study.

* * * *

[112] Q . . . As I understand it, you work for a corporation?

A I have what's called a professional corporation. You can call it that.

Q What is the name of your corporation?

A Daniel T. Teitelbaum, M.D., Inc.

Q And you own 100 percent of the stock in the corporation?

A Yes, that's correct.

[113] Q And that's where you receive your income?

A Yes.

Q And you have 16 employees?

A That's correct.

Q And do they all work there in the Denver office?

A Yes.

Q And I understood earlier that you—at least one of them is a paralegal?

A That's correct.

* * * *

[115] Q Well, you say it's none of my business, but you've charged me $4,000 in advance to take your deposition. So far I've been here three hours and 15 minutes—

A I'll be happy to give you a refund from 1:30 on.

* * * *

[117] Q Does your office have a brochure that you use for advertising purposes?

A Never advertised.

Q You do not advertise of any kind?

A The last thing in the world I'd need would be to advertise. I'd drown.

* * * *

[118] Q Now, you referred to this book, and I think specifically this book is called *The International Program on Chemical Safety, Environmental Health Criterion 140, PCBs, Second Edition.*

A Right.

Q And you referred, I believe, to page 478.

A Right, the summary page.

Q 477, which is paragraph—all right, 478 which is the first—let me see if I can find this. First paragraph, which says that PCBs were evaluated by IARC in 1977 and 1987. In 1987 the IARC concluded that because the role of impurities in PCBs and the carcinogenicity could not be excluded and because of the lack of knowledge on dose response relationships, the evidence from epidemiological studies is limited. However, the evidence of carcinogenicity in laboratory animals is sufficient, taking the combined evidence from human and experimental

animal studies, the IARC group concluded that PCBs are probably carcinogenic for humans.

A Right.

Q And you agree with that statement?

A Yes, I do.

[119] Q On the preceding page in paragraph 926, appraisal, it says that some epidemiological studies on occupationally exposed workers—and is that Yushall—

A Yusho, yes.

Q Yusho patients indicate an association between PCB exposure and cancer especially with regard to hepatobiliary—

A Yes.

Q —tumors; however, no definite conclusions can be drawn from available data because of the small number of deaths in the population studies, the lack of clear dose response relationships in the occupational studies, and the difficulty of evaluating the effects of other compounds present in PCBs.

A Yes.

Q Do you agree with that?

A Yes.

* * * *

MR. COCHRAN: Let's go back on the record. Can we agree and stipulate that what we're now going to mark as 7A is a more up-to-date list of the legal appearances by Dr. Daniel T. Teitelbaum?

MR. WARSHAUER: Subject to the restrictions of his prior testimony as to how it's prepared.

* * * *

[Teitelbaum Ex. 11-A]

JOHN D. ARCHBOLD MEMORIAL HOSPITAL

Gordon Avenue at Mimosa Drive
Thomasville, Georgia 31792

HISTORY AND PHYSICAL DR. MORLEY
Page 1

JOINER, ROBERT
MR# 235149 HOSP SVC: ONM
PT# 102093895

ADMITTED: May 03, 1992

PRESENT ILLNESS: Mr. Joiner presents to clinic with fever and shortness of breath, significant nasal discharge with daily fevers.

PAST MEDICAL H ISTORY: Allergic to sulfa, Tylox and codeine. Has had no major illnesses. Last chemo ended on January 1992 for intensive treatment of small cell lung carcinoma stage III. He has remained disease free subsequently.

FAMILY HISTORY: Negative for any evidence of carcinoma, positive for heart disease.

SOCIAL & PERSONAL HISTORY: Negative for cigarettes and alcohol use although the patient did smoke one to two packs a day for 15 years.

PHYSICAL EXAMINATION: The patient is alert and oriented, but is complaining of severe nausea and vomiting, doubled up because of abdominal cramping, pain. Neck reveals no adenopathy or thyromegaly. HEENT reveals Horner Syndrome of left eye as before. The rest of the cranial nerves are essentially within normal limits. CHEST: Clear to auscultation and percussion bilaterally although left lung sounds are decreased as previously because of surgical changes and radiation fibrosis. ABDOMEN: Diffusely nontender. No organomegaly or masses

and normal bowel sounds. EXTREMITIES with no clubbing, cyanosis or edema. LABORATORY: Pending.

IMPRESSION:

1) Patient with small cell lung cancer in stage III.

PLAN:

The patient admitted to rule out recurrent disease, IV antibiotics administered because of fever.

/s/ Walter B. Morley
WALTER B. MORLEY, M.D.

RBM/sm

6/21/92 @ 1:26p
6/21/92 @ 3:10p

[Defendant's Exhibit 7]

LEGAL APPEARANCES BY DR. DANIEL T. TEITELBAUM

CALENDAR YEAR 1983

DATE	CASE	TYPE OF APPEARANCE
1983	Jones v. Penwalt	Trial Testimony
05/18/83	Perry v. Summers	Trial Testimony
05/26/83	Charlesworth v. Davies	Deposition
08/04/83	Gouge v. Celestial Seasoning	Work Comp. Hearing
08/15/83	Sierra v. Sunstrand	Work Comp. Hearing
08/22/85	Ramon Lewis v. Aerojet General	Work Comp. Hearing
10/15/83	Amon v. Manville	Deposition
11/01/83	Pettis v. Boston Hospital	Trial Testimony
11/14/83	Martin Adams v. Granite	Work Comp. Hearing
11/09/85	Schwerin v. Cyanamid	Trial Testimony
11/83	People v. Templeman	Trial Testimony

CALENDAR YEAR 1984

01/11/84	Manly v. Zaki	Trial Testimony
01/12/84	Galloway v. Denver Metal Finishing	Work Comp. Hearing
01/25/84	Ruiz v. Chloride Battery	Deposition
02/01/84	Richner v.	Work Comp. Deposition
02/02/84	People v. Hobart & Steed	Trial Testimony
03/05/84	Jim McDuffie v. Burl. No. Railroad	Work Comp. Deposition
04/18/84	People v. Mary Hoffner	Trial Testimony
04/24/84	Agent Orange Plaintiffs v. Dow	Deposition
05/08/84	Schledowitz v. Schering	Deposition
05/14/84	Tejeda v. Eagle Chemical	Deposition
05/21/84	Skyring v. Wyeth	Deposition
06/11/84	Jourdan v. Syntex	Deposition
06/14/84	Broussard et al., v. Velsicol	Deposition
06/18/84	Gann v. Schwartz, et al.	Deposition
07/05/84	People v. Hoffner	Trial Testimony
07/10/84	Katsounakis v. Robertson Assoc.	Work Comp. Hearing
07/11/84	People v. Houston	Trial Testimony

DATE	CASE	TYPE OF APPEARANCE
07/23/84	Deasy v. U.S.	Deposition
07/24/84	Hunter v. International Harvester	Work Comp. Deposition
07/25/84	Pierce v. Anaheim Drug	Deposition
08/01/84	Popick, et al. v. Manville, et al.	Deposition
08/07/84	Genette v. Syntex	Deposition
10/02/84	George Maddox v. Colo. Ute	Work Comp. Hearing
10/10/84	Wallace Anderson v. Manville	Deposition
11/19/84	In RE: Jay F. Morris, D.D.S.	Administrative Hearing
12/05/84	Schmunk v. Merck, et al.	Deposition
	CALENDAR YEAR 1985	
01/08/85	Skeen v. Monsanto	Deposition
01/12/85	Clausen, et al. v. Texaco	Deposition
02/15/85	Esquibel v. Vail Med. Center	Deposition
02/21/85	Gaan v. Schwartz, et al.	Trial Testimony
03/22/85	Kast v. Upjohn	Deposition
04/03/85	Sturdy v. Hansen, et al.	Deposition
04/15/85	Hickman v. Thompson Company	Deposition
05/14/85	Kruse v. Ralston Purina	Trial Testimony
05/24/85	Ashley v. Scientific Applications	Trial Testimony
05/28/85	Deasy v. U.S.	Trial Testimony
06/04/85	Broussard et al. v. Velsicol	Trial Testimony
06/18/85	Russell v. Coacher	Deposition
06/19/85	Glaser v. Ashland Oil, et al.	Deposition
07/03/85	Daly v. Scheared, et al.	Deposition
07/19/85	Sauter v. Chestnut	Deposition
08/05/85	Durham v. Western Paving	Work Comp. Deposition
09/06/85	Blessing v. Dow	Deposition
09/10/85	Carman v. Sherwin Williams	Deposition
09/30/85	Donald Ward v. City of Mitchell	Deposition
10/02/85	Kerr v. State Hospital, et al.	Deposition
10/11/85	Hinojos v. O'Dell	Deposition
11/07/85	People v. Goode	Trial Testimony
12/06/85	Henderson v. Texaco	Deposition
	CALENDAR YEAR 1986	
01/06/86	Lancaster v. Newberry	Deposition
01/06/86	O'Neill v. Zoecon	Deposition
01/22/86	Jason Enos	Deposition
02/13/86	James Baisley	Deposition

DATE	CASE	TYPE OF APPEARANCE
03/04/86	Simon, Ledford, Duhon	Deposition
03/11/86	Summers	Deposition
03/27/86	Grenier v. Dow	Deposition
03/14/86	Formaldehyde Hearings	Hearing
04/03/86	Benzene Hearings	Hearing
05/16/86	Brown v. Snodgrass	Deposition
05/23/86	Sharon Lee	Deposition
06/23/86	Kast v. Upjohn	Trial Testimony
06/26/86	Burke v. Continental Can	Deposition
07/02/86	Robideaux	Deposition
07/17/86	Pierce v. Anaheim, et al.	Trial Testimony
07/22/86	Kitzman	Trial Testimony
08/05/86	Diamond v. Dilly	Deposition
08/06/86	Cook, et al. v. Fashion Carpets	Deposition
08/07/86	Charles Wright	Deposition
08/08/86	Kevin Goode	Deposition
08/08/86	Pete Zamara	Deposition
09/04/86	Nelson v. Scott's Pest Control	Deposition
09/09/86	Charles Wright v. Gulf Oil, et al.	Deposition
09/17/86	Hickman v. Thompson Co.	Deposition
09/22/86	Leslie Payne	Deposition
09/23/86	John Colcord	Deposition
09/29/86	House v. Aeroplane Club	Deposition
10/02/86	State v. Aoki	Trial Testimony
10/15/86	Geist v. Coors	Deposition
10/17/86	Baisley	Trial Testimony
10/21/86	Skeen v. Monsanto	Trial Testimony
10/28/86	Plaintiffs v. Union Pacific	Deposition
10/29/86	Roberta Sorensen	Trial Testimony
11/07/86	Bittle v. Dahlberg	Deposition
11/24/86	Brancucci & Langarek	Deposition
11/26/86	Robert Thompson	Deposition
12/15/86	David and Catherine Wells	Deposition
12/16/86	Griffin	Deposition
12/19/86	Bittle v. Dahlberg	Deposition
	CALENDAR YEAR 1987	
01/03/87	Ziegler v. Gulf States	Deposition
01/09/87	Summers	Deposition
01/30/87	Hofmeister	Deposition
02/09/87	Francis Larrew	Deposition
02/13/87	Cassens v. Upjohn	Deposition
02/13/87	Ronald Reef	Deposition
02/24/87	Burke v. Continental Can	Deposition
03/02/87	Runge v. Hecker, Ming Dynasty	Deposition
03/12/87	Stout	Deposition

DATE	CASE	TYPE OF APPEARANCE
03/24/87	Laboratory Standards	Hearing
03/25/87	Greene v. ARCO	Deposition
03/31/87	Lloyd Wright	Deposition
04/06/87	Colorado v. Idarado	Deposition
04/20/87	Scott v. Monsanto	Deposition
04/24/87	Snapka v. Big Red	Deposition
04/29/87	Barbara Nemec	Trial Testimony
05/11/87	Raymond Swanson	Deposition
05/12/87	James Sipes/Velma Porter	Deposition
05/21/87	Sargent et al.	Deposition
05/27/87	Paaka v. Coors	Trial Testimony
05/28/87	Jaspar Wages	Deposition
05/30/87	Southard	Deposition
06/03/87	Colorado v. Idarado	Trial Testimony
06/04/87	James Sipes/Velma Porter	Trial Testimony
06/05/87	Abernathy v. Mopac	Deposition
06/10/87	Snapka v. Big Red	Trial Testimony
06/12/87	Frank Defier	Deposition
06/15/87	Greenhill v. Dow	Deposition
06/16/87	Moss v. Charter Oak	Deposition
08/12/87	Kracht & Galletin	Deposition
08/12/87	Gilpatric Family	Deposition
08/13/87	Southard	Trial Testimony
08/18/87	Pikeville, Kentucky v. Monsanto	Deposition
08/24/87	Eileen Newblock	Deposition
08/26/87	Scott et al. v. Monsanto	Trial Testimony
09/16/87	Barnett et al. v. Hurst Graphics	Trial Testimony
10/07/87	Larry Unger & Clarence Pettit	Deposition
10/08/87	Virgil Dotty	Deposition
10/09/87	Santiago v. Firestone	Deposition
10/12/87	CAPCO Plaintiffs	Deposition
10/14/87	Eileen Newblock	Trial Testimony
10/16/87	Terry Bronder	Deposition
10/19/87	Lewis Gazaw	Deposition
10/20/87	Charles Corder	Deposition
10/21/87	Lloyd H. Sweger	Deposition
11/12/87	Clarence Pettit v. Armstrong World	Deposition
11/30/87	Greenhill v. Dow	Trial Testimony
12/2/87	USA v. Protex	Trial Testimony
	CALENDAR YEAR 1988	
01/15/88	Gazaw v. Air Products et al.	Deposition
01/16/88	Comeaux v. Sabine Propellor	Deposition
02/01/88	Santiago et al. v. Firestone et al.	Trial Testimony
02/27/88	Lloyd H. Sweger	Deposition
04/22/88	De La Garza v. Ashland Chemical	Deposition

DATE	CASE	TYPE OF APPEARANCE
04/23/88	Griffen v. Engineering Professional	Trial Testimony
04/24/88	Cook v. Armstrong	Trial Testimony
04/25/88	Jacobs v. Union Carbide	Deposition
04/26/88	Edmon Benavides	Deposition
04/26/88	James L. Nations	Deposition
07/07/88	Madra Weaver	Deposition
07/12/88	Skeen v. Monsanto	Deposition
09/15/88	Williams v. Memorial Hospital	Deposition
09/15/88	Santiago v. Firestone	Deposition
09/27/88	Miller v. Amax	Deposition
10/11/88	Evanson v. Osmose, et al.	Deposition
10/14/88	Wyels et al v. Neoplan	Deposition
10/26/88	Karos v. Vertac	Deposition
10/31/88	Santiago v. Firestone	Trial Testimony
11/14/88	Arvel Day v. Union Carbide	Trial Testimony
11/15/88	Newsome v. Texas City Refining	Deposition
11/29/88	Moss v. Charter Oaks	Deposition
12/05/88	Lockhart, Stricker, Kerr, Donohoe	Trial Testimony
12/09/88	Larry J. White	Deposition
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[Defendant's Exhibit No. 7-A]

LEGAL APPEARANCES BY DR. DANIEL T. TEITELBAUM

CALENDAR YEAR 1989

01/04/89	Alexander, Amon, Martinez	Deposition
01/20/89	Skeen v. Monsanto	Trial Testimony
01/30/89	John A. Martinez	Trial Testimony
01/31/89	Landrum v. Litton Systems	Deposition
02/08/89	Swartz v. Hewlett Packard	Mediation Testimony
02/15/89	Slaughter v. Farm & Home (Brio Site)	Deposition
03/03/89	Friel v. Paint Companies	Deposition
03/08/89	Stilley v. Katy SWD	Deposition
03/10/89	J.D. & Gladys Sanders v. Binford	Deposition
03/21/89	Dee & Charlene Byrnes	Trial Testimony
03/29/89	Nelson v. Farmland	Deposition
04/19/89	Cook v Fashion Carpets	Trial Testimony
04/26/89	Hynes v Armstrong World Industries	Trial Testimony
05/01/89	Askew v Red Devil Lye	Video Testimony
05/04/89	Kneppler v Alamo Barge	Deposition
05/09/89	Friel v Paint Companies	Trial Testimony

DATE	CASE	TYPE OF APPEARANCE
06/07/89	Nelson v Butler Paper	Deposition
06/22/89	Franco v Duraspan	Deposition
06/28/89	Fraley v Hospital Corp. of Am.	Deposition
07/11/89	Franco v Duraspan	Trial Testimony
07/20/89	Tice v Protex	Deposition
08/01/89	Howard Henderson	Video Testimony
08/03/89	Sipole v Union Carbide	Deposition
09/08/89	Hansen v Chevron	Deposition
09/21/89	Clarence J. McCall	Deposition
11/20/89	Hughes v Burlington Northern	Deposition
11/21/89	Porter v Union Oil CO	Deposition
11/27/89	Droddy v Texaco	Deposition
12/05/89	Brio Site	Trial Testimony
12/13/89	City of Laporte	Trial Testimony
	CALENDAR YEAR 1990	
01/04/90	Smith v Sabine Towing	Deposition
01/05/90	Fairley v Texaco	Deposition
01/08/90	Hansen v Chevron	Trial Testimony
01/12/90	Culp v Curtain Matheson, Inc.	Deposition
01/13/90	Cordova v Judwin	Deposition
01/16/90	Morrison v Eli Lilly	Deposition
01/22/90	Droddy v Texaco	Deposition
01/23/90	Baker v Armstrong Indus Inc.	Trial Testimony
01/24/90	Hudson v C F & I	[Deposition]
01/30/90	Quigg v Amoco	Deposition
02/06/90	Stone v Varn et al	Deposition
02/19/90	RE: Thomas Martin	Deposition
02/22/90	RE: Harold Washington	Trial Testimony
02/28/90	Wright v General Dynamics	Deposition
03/12/90	Harris v General Dynamics	Deposition
03/22/90	RE: Robert Hardy	Deposition
04/16/90	RE: ED Casey	Deposition
04/17/90	Zehr v Hoechst Celanese	Deposition
04/19/90	David F. Vaughn	Video Testimony
04/20/90	RE: ED Casey	Video Testimony
04/24/90	RE: Sorrells	Deposition
05/22/90	Zehr v Hoechst Celanese	Trial Testimony
05/23/90	Kucharski & Remmick	Trial Testimony
05/25/90	Flores et al. v Judwin	Trial Testimony
06/01/90	Paula Peters v. G.C. Hanford	Deposition
07/09/90	Davis v Avondale	Deposition
07/10/90	Robert Jenkins	Deposition

DATE	CASE	TYPE OF APPEARANCE
07/11/90	Keister v Dow	Deposition
07/18/90	Renaud v Martin Marietta	Summary Judgment Testimony
07/23/90	Gail Crull	Deposition
07/24/90	Akin & O'Brien	Deposition
07/30/90	Judy Cooper v State Farm	Deposition
08/07/90	Ray Spurlock	Deposition
08/14/90	Hofer v Amoco	Deposition
08/21/90	Carol Davis v Avondale	Trial Testimony
08/23/90	Keister et al. v Hercules	Trial Testimony
09/12/90	Ackerson et al. v Dow	Deposition
09/14/90	Green et al. v Marathon Oil	Deposition
09/18/90	Linda Atchley	Trial Testimony
09/21/90	Powell v Chevron	Deposition
09/25/90	Sean Kostelecky v Dow	Deposition
09/26/90	Arevalo et al. v Tide	Deposition
09/27/90	Gary Evenson	Trial Testimony
10/08/90	Stringfellow	Deposition
10/09/90	Betty Mayberry	Deposition
10/10/90	Cathey v Exxon	Deposition
10/11/90	Mullens v Wyeth Labs	Deposition
10/12/90	Mundo v General Dynamics	Deposition
10/24/90	Newman v Stringfellow	Trial Testimony
10/26/90	Buchaj v Texaco	Deposition
11/07/90	Green v Marathon	Trial Testimony
11/15/90	Linda Atchley	Trial Testimony
11/16/90	Rocha v Insta Foam Products	Deposition
11/27/90	Clair Adams, et al. v Westinghouse Electric, et al.	Deposition
12/10/90	Dole v Interstate Lead. OSHA	Trial Testimony
12/12/90	Sean Kostelecky	Trial Testimony
12/20/90	Sec. of Labor v Asarco OSHA	Deposition
	CALENDAR YEAR 1991	
01/10/91	Daniel McKee	Deposition
01/25/91	Larkin v Dow Chemical	Deposition
02/04/91	Johnson v Halliburton	Deposition
02/15/91	Chargois v Shell Oil Co.	Deposition
02/20/91	Daigle, et. al. v Shell Oil	Deposition
02/22/91	Wilbur Smith v Allied Signal	Deposition
02/26/91	Bartlett v Browning	Deposition
02/28/91	Pargmann v SPTC	Deposition
03/06/91	Wing v Shell Oil Co.	Deposition
04/23/91	Kolster v Union Carbide	Deposition

DATE	CASE	TYPE OF APPEARANCE
04/25/91	Jones v El Paso Products Co.	Deposition
05/15/91	Newman v Stringfellow, et al.	Deposition
05/28/91	Schamper v Dow	Deposition
06/04/91	Schamper v Dow	Evidentiary Deposition
06/21/91	Gerald Sheets	Deposition
06/24/91	Dupriest v Demco, Inc.	Deposition
07/02/91	Wyatt-Jose v. Eli Lilly	Deposition
07/09/91	Harvey v. Chevron	Deposition
07/09/91	Wycoff, et al. v. Chevron	Deposition
07/15/91	Lancaster v. Orkin	Deposition
07/18/91	Eubanks v. Shell Oil Co.	Deposition
07/23/91	Quante v. W.R. Grace, et al.	Deposition
07/24/91	Benoit v. Dixie Carriers, Inc.	Deposition
08/28/91	Best v. Walgreen Laboratories	Deposition
09/19/91	King, et al. v. Ameron Inc., et al	Deposition
09/20/91	Ellis, et al. v. Oxy Oil, Inc.	Deposition
10/18/91	Eubanks v. Shell Oil	Deposition
11/21/91	Fontenot v. ARCO	Deposition
11/22/91	Wright v. Mobil Chemical	Deposition
12/05/91	Oliver v. Kaiser, et al	Deposition
	CALENDAR YEAR 1992	
01/14/92	Wm. White v B.P. Chemicals, et al	Deposition
01/15/92	Larkin, et al v Dow Chemical Co.	Trial Testimony
03/05/92	Siemion v. USX, et al.	Deposition
03/19/92	Hathaway v. Flanders	Deposition
05/11/92	Acosta, et al v. Monsanto, et al	Deposition
05/13/92	Lancaster, et al v. Orkin	Trial Testimony
05/14/92	Previtt, et al v. Howard Hanna Real Estate Services, Inc.	Video Trial Testimony
05/20/92	James Infinger v. Ashland, et al	Deposition
05/21/92	Ronford Styron v. Shell, et al	Deposition
05/27/92	Shult, et al. v. Champion International	Deposition
05/28/92	Robert Escamilla, et al v. ASARCO, Inc.	Class Action Certification Hearing
06/04/92	O'Connor v. Mobile Chemical Corp	Deposition
06/10/92	Moyer v. Dow, et al	Deposition
07/27/92	Donald Campbell	Trial Testimony
08/05/92	Phillip Wilson	Deposition
08/06/92	Williams v. Burgess	Deposition
08/07/92	Shults v. Champion	Deposition
08/10/92	Jack Firmature	Deposition
08/17/92	Lockheed Litigation	Deposition

DATE	CASE	TYPE OF APPEARANCE
09/11/92	Escamilla v. Asarco	Deposition
09/16/92	Shults v. Champion	Trial Testimony
10/01/92	Aiken v. Unocal	Deposition
10/05/92	Donald F. Allen, et al.	Deposition
10/12/92	Steve LeBlanc	Deposition
11/02/92	Adkins v. Ashland Oil	Deposition
11/16/92	Lockheed Litigation	Trial
11/21/92	Jenna Nomeland	Deposition
12/04/92	Steve Marley	Deposition
12/07/92	Aiken v. Unocal	Deposition
12/22/92	Kent Woods v. Goodrich	Deposition
12/29/92	Cutshaw v. Weyerhaeuser	Deposition
	CALENDAR YEAR 1993	
01/05/93	Joseph P. Fiorella	Deposition
01/16/93	Richard Hammond	Deposition
01/20/93	Newman v. Stringfellow	Deposition
01/21/93	Lockheed Litigation	Trial
01/22/93	Belma Wright	Trial
02/17/93	R. Escamilla v. ASARCO	Trial
02/18/93	Elmer Monk	Deposition
02/19/93	Douglas Hoskins v. Oxy Petrochemical	Deposition
02/20/93	William Williams v. Burgess Products	Deposition
03/17/93	Cutshaw v. Weyerhaeuser	Trial
04/13/93	William Stagner	Deposition
04/14/93	Tom Morris v. Burlington Northern R.R.	Deposition
04/15/93	Chester Elrod v. Groendyke Transport	Deposition
04/16/93	Ferrel Fautheree	Deposition
04/19/93	Newman v. Stringfellow	Trial
04/23/93	Skaggs v. Simpson Lumber	Deposition
04/28/93	Diagle v. Shell	Deposition
04/29/93	Jack Walker	Deposition
05/05/93	Robert Moyer v. Dow	Deposition
05/11/93	Wilson Simon	Deposition
05/13/93	William Lee v. Interstate Lead	Deposition
05/28/93	Douglas Hoskins v. Oxy Petrochemicals	Trial
06/15/93	Kingsmill Community Water Supply v. Hoechst Corporation	Deposition
06/24/93	Duke Johnson v. Hoechst Celanese	Deposition
07/15/93	Carnival Cruise Lines	Deposition
07/27/93	J.W. Bartlett v. Browning-Ferris Industries Chemical Services, Inc.	Deposition
09/18/93	Billy Bane Smith/John Crawford v. Hartford Accident and Indemnity Co.	Deposition
10/05/93	Roy Adams v. International Paper Co.	Deposition

[Defendant's Exhibit No. 7-B]

10/06/93 — Daniel Thau Teitelbaum, M.D., P.C.
SELECTED DATA — CLIENT TIME DIARY

Init	Date	Hours	Description	Rate	Fees	Cumulative Tax	Code	Loc	Seq	Job
CLIENT #		33	Warshauer, Michael J.							
MATTER #		2578	Joiner vs. Westinghouse, Monsanto & GE							
EJ	07/06/93	1.00	Create File	50.00	50.00	50.00	19	B	1	H730
JLH	07/06/93	0.30	Index & file case material	90.00	27.00	77.00	29	B	3	H730
JLH	07/06/93	0.50	Drafting document	90.00	45.00	122.00	12	B	4	H730
JLH	07/07/93	0.20	Drafting correspondence for case	90.00	18.00	140.00	5	B	5	H730
JLH	07/07/93	0.30	Preparation of engagement Letter	90.00	27.00	167.00	21	B	6	H730
JLH	07/08/93	0.20	Research	90.00	18.00	185.00	7	B	7	H730
DTT	07/14/93	4.00	Consultation—meet with Mr. Holland and Mr. and Mrs. Joiner.	625.00	2,500.00	2,685.00	15	B	2	H730
JLH	09/01/93	0.20	Phone converation/follow up re: case	90.00	18.00	2,703.00	34	B	10	H930
JLH	09/09/93	0.30	Review document/correspondence	90.00	27.00	2,730.00	14	B	11	H930
JLH	09/13/93	0.30	Scheduling	90.00	27.00	2,757.00	56	B	12	H930
DKS	09/14/93	0.30	Compiling Literature/material for case	50.00	15.00	2,772.00	23	B	9	H930
JM	09/14/93	2.00	Professional Research Asso.-depo summary	150.00	300.00	3,072.00	74	B	15	H930
JM	09/15/93	2.50	Professional Research Asso.-depo summary	150.00	375.00	3,447.00	74	B	16	H930
JM	09/17/93	4.50	Professional Research Asso.-depo summary	150.00	675.00	4,122.00	74	B	17	H930
JLH	09/20/93	0.40	Preparation of deposition Letter	90.00	36.00	4,158.00	24	B	13	H930
JLH	09/20/93	0.20	Scheduling	90.00	18.00	4,176.00	56	B	14	H930
EJ	09/27/93	1.30	Library maintenance	50.00	65.00	4,241.00	36	B	8	H930
TOTAL MATTER		18.50								
TOTAL		18.50				4,241.00				

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

The deposition of DR. LARRY ROBERTSON was taken before Jennifer K. Young, Court Reporter and Notary Public in and for the State of Kentucky at Large, at Hyatt Regency, 400 Vine Street, Washington Room, Lexington, Kentucky, on Friday, October 8, 1993, commencing at the approximate hour of 10:00 a.m. Said deposition was taken on behalf of the Defendant, Monsanto, by agreement, for purposes of discovery and all other purposes as permitted by the Federal Rules of Civil Procedure.

* * * *

[5] The witness, DR. LARRY ROBERTSON, after first being duly sworn, was examined and testified as follows:

* * * *

[7] Q4 Let's identify which two articles you have in front of you.

A I'd be happy to do that. Let's take the first one first. This is an article by Lucy Anderson and other authors entitled, "effects of Polychlorinated Biphenyls on Lung and Liver Tumors Initiated in Suckling Mice by N-Nitrosodimethylamine," published in the Journal of the National Cancer Institute, volume 71, July 1983, pages 157 through 163.

* * * *

Q5 And the next article, please.

[8] A The second article that I am looking at is also an article by Lucy Anderson and other co-workers entitled, "Effects of a Single Dose of Polychlorinated Biphenyls to

Infant Mice on N-Nitrosodimethylamine-initiated Lung and Liver Tumors," published in the International Journal of Cancer, volume 38, pages 109 to 116 in the year 1986.

* * * *

Q6 When were you first contacted by someone about Mr. Joiner's case?

A I believe the initial contact was initiated by Michael Warshauer approximately the spring of last year.

Q7 What did Mr. Warshauer tell you about Mr. Robert Joiner, if anything?

A Basically that this gentleman is suffering from lung carcinoma, was currently—or at that time was in very poor health. He had an occupational [9] history of exposure by virtue of the fact that he was employed in the electric power industry in the capacity of repairing transformers, had suffered exposure to halogenated aromatic hydrocarbons. I was also told that he had, that is Mr. Joiner, had a history of smoking, cigarette smoking.

Q8 Anything else?

A That was the gist, I believe, of the conversation.

Q9 Were you told what kind of lung cancer he had?

A I don't recall.

Q10 Have you seen his medical records?

A Yes, I have seen them.

* * * *

[12] Q22 Have you ever seen Mr. Joiner?

A No, I have not.

Q23 Have you ever been to the place where he worked?

A No, I have not.

Q24 Have you been informed as to what kind of fluids were in the transformers upon which Mr. Joiner was working?

A Through the attorney, Michael Warshauer.

Q25 What fluid do you understand to be in the—

A The fluids were various mineral oils containing varying concentrations of PCB.

Q26 Anything else, any pure PCB fluid in transformers?

A I have no knowledge of that.

[13] Q27 Now can you tell me what small cell lung cancer is?

A I'd like to say from the outset that it is not my intention to give statements regarding clinical aspects of this case. I am a research scientist. My knowledge includes the mechanism of toxicity of polyhalogenated aromatic hydrocarbons, specifically in animal models. I have most of my adult life worked in the research laboratory. I am a Ph.D. and not an M.D. I would very much like to limit my statements to non-clinical aspects of this case as relates to mechanisms of carcinogenicity in the context of the relevant scientific literature.

Q28 Can you tell me what small cell lung cancer is?

A Not histologically nor—no. I cannot tell you what it is.

Q29 Can you tell me how many different kinds of cancer one may find in the lung from various causes?

A There are a multiplicity of cancers arising from a number of different cell types, from a variety of different causes. That is general knowledge[. . . .]

* * * *

[14] Q30 . . . As far as you know, is there any credible evidence from a scientific probability point of view that PCBs initiate small cell carcinoma in the lung in humans?

A PCBs are generally not recognized as initiating agents but rather are widely accepted as promoting agents in a number of tissues.

Q31 So the answer to that question is no?

A The answer to the question as it was stated if PCBs have been shown clearly to be initiators of carcinogenesis is no. They are rather classified as promoting type carcinogens, not initiating type carcinogens.

Q32 Now I want to be perfectly clear about what I am asking you. I'm going to ask you the same question

about promotion. Is there any credible evidence as a scientific probability that PCBs promote, and I emphasis, small cell carcinoma in the lung in humans?

A I know of none in that context, no, in humans.

Q33 Do you know of any in animals? This is with respect to small cell carcinoma in the lung.

A I know of studies, and we have identified one of [15] them, in which PCBs promote DMN-initiated carcinoma in the lung of mice.

Q34 Is that article small cell carcinoma, no, is it?

A It's not identified as such, that's correct.

* * * *

Q35 [. . .] Along that line, what opinions do you expect to give in this case?

A On the basis of the articles which we will discuss in which the propensity of PCBs or the characteristic of PCBs to promote initiated carcinoma in the lung of mice on the one hand, and on the other hand, the very unusually young age of which this individual, Robert Joiner, developed [16] lung carcinoma. I expect, based upon of course what further information comes to me, that is I qualify my expectation on that basis, that my—my expert opinion will be that this gentleman developed lung carcinoma at a very young age because the onset of that disease was promoted, supported, accelerated by his exposure to halogenated aromatic hydrocarbons.

Q36 In the first place, what was the initiator of his lung cancer in your opinion, cigarette smoking?

A It's certainly a possibility. Cigarette smoke is known to have components which have—which are stronger initiators than they are promoters. That is one reason that individuals who develop lung cancer from cigarette smoking require almost a lifetime of cigarette smoking before they develop lung cancer. Years of exposure, decades of exposure to cause sufficient damage within the lung cells that cell division takes place fixing the damage that was initially incurred, that is the initiating capacity, requires a long period of promotion to

lead to the overt disease. Mr. Joiner had a relatively short time span between his smoking exposure and the onset of the disease, unusually short. Something must have accelerated [17] that process and that something was most likely the chemicals to which he was exposed in the work place.

* * * *

[18] Q42 When you gave me your opinion earlier about it being—I don't know what the words were you used but you said something about it being a promoter in his case because of his young age or something of that nature.

A The facts are that he developed as a young man, I believe, with 37 years a carcinoma of the lung, a type that is, so I've been told, often associated with cigarette smoke. That in itself indicates to me that some other factor may have played a role in accelerating this process.

Q43 As I understand it, you cannot point to anything in [19] the literature that says that small cell lung cancer has been produced in any animal model.

A No, I cannot at this time.

Q44 Is there any epidemiological evidence in humans that PCBs are promoters in small cell lung cancer?

A I'm not aware of that.

Q45 You're not aware of any?

A I'm not aware of any.

Q46 From your background as I understand it, your field is toxicology.

A That's correct.

Q47 Are you Board certified?

A No, I'm not.

* * * *

[20] Q49 And I believe you've earlier told me that you're not a medical doctor.

A I am not a medical doctor.

Q50 You will not give any medical opinions.

A Would not give any clinical opinions.

Q51 Any clinical medical opinions; is that correct?

A I would prefer if you just separated things into clinical and basic research.

Q52 Your field then is basic research—

A That's correct.

Q53 —in animals.

A In animals, that's correct.

Q54 You're not an immunologist?

A I am not a immunologist.

Q55 You're not an epidemiologist?

A I have experience with cohorts but I am not trained as an epidemiologist.

Q56 You're not a veterinarian.

A I'm not a veterinarian. Maybe I should qualify the statement about the epidemiology. I have, of [21] course, taken courses in epidemiology and have a master's degree in public health from the University of Michigan, which gives me some experience in looking at public health related phenomena, whether that's—public health by definition, of course, deals with a population as opposed to the individual.

Q57 Any other opinions that you're going to give about Mr. Joiner specifically?

A I would like to limit my testimony to what's in the scientific literature, primarily mechanisms, toxicity relating to polyhalogenic aromatic hydrocarbons and those aspects of this case.

Q58 When you do scientific research, do you usually subscribe to some sort of scientific method—methodology?

A Of course.

Q59 Would you please describe that in detail for me? Science often starts with a question or a hypothesis. Mechanisms are formulated for addressing this question or hypothesis, proving it or disproving it. Experiments are designed. Animals, in my case, are ordered. Treatments are administered. Animals are sacrificed. Measurements are made. The question or hypothesis [22] is accepted, rejected or the data is insufficient to do either of those two things.

Q60 Earlier you had, I think, two papers marked that you had brought with you. Both of these papers are offered in part by Lucy M. Anderson.

A That's correct.

Q61 And when she refers to—looking here at Deposition Exhibit No. 2, to suckling mice, are those baby mice? What does that mean?

A That's correct. Those are mice that are suckling. That is they are drinking milk from their dams, from their mothers.

Q62 She dosed these mice. What kind of dose did she give them?

A First of all, she treated the dams, the mothers with PCBs on their ninth—these were pregnant dams, on their 19th day of gestation. The suckling mice themselves were treated either on day four or on day 14 with a potent alkylating agent, a carcinogen, dimethylnitrosamine.

Q63 And these little suckling mice—

A They grew up, yeah. Then they were killed either at 28 weeks of age or they were killed at 18 months of age.

Q64 They had some production of tumors; is that [23] correct?

A That's correct.

Q65 Was she able to reproduce that in adult mice?

A That question is not very clear to me. This study which was done in 1983, to my knowledge, was not attempted to be reproduced. And this second paper does not purport to be an attempt to reproduce this study. The design of these two studies are different.

Q66 Did you understand the question because I understand that she was not able to make the leap from the suckling mice or baby mice to adult mice? That's eitther true or not.

A Or the other alternative is I don't know.

Q67 Is that your answer?

A I don't know at this time. I do not—I cannot remember the specific paper in which exactly this experiment was attempted in adult mice. That paper may exist and I'll be happy to look at it if you can produce it.

* * * *

[25] Q72 First of all, do you know of any human epidemiological studies that relate to small cell lung cancer?

A Epidemiological studies don't usually relate to a single end point. Usually you look at a cohort for a variety of symptoms or signs that may occur as a result of an experience like an exposure to a toxic chemical.

Q73 Do you know of any that relate in humans to lung cancer in general that would illustrate that lung cancer is promoted by or encouraged or whatever by being exposed to PCBs?

A I am not aware of that exact kind of study. I think such studies have been attempted but I do not think they are published. They may be in fact ongoing. I think they would be very interesting to the scientific community to see those. I do know of an epidemiologic study where the joint function [26] of asbestos and cigarette smoke was clearly demonstrated.

Q74 Do you know about any—the answer about PCBs then is no?

A I'm not aware of such studies. I hope such studies will be done. I would look forward to reading such studies.

Q75 Now in animal work and specifically in the two papers that we had marked earlier, two and three I believe are the numbers, were the tumors produced in relation to the dose given?

A Yes.

Q76 How high a dose was given? Let's take Exhibit 2 first and then Exhibit 3. What were the range of dosage I should say?

A In the Exhibit 2, there was a—appears to be a single dose of 500 milligrams per kilogram whereas in Exhibit 3, there were a range of doses up to 500. That included a dose of 50, 250 and 500 milligrams per kilo-

gram of Aroclor 1254, I believe in both cases, yes. And I believe these were also single administrations in all cases.

Q77 When you say single administration, one dose?

A Yes.

Q78 How was the dose administered?

[27] A From a toxicologic point of view, that's not an exact definition. In this case it's much better to mention the applied amount. Call it a dose, that's fine. How were they administered? In the—

Q79 Given in the feet or intravenously or what?

A In Exhibit 2 the PCB was administered to the dam, the pregnant dam on the 19th and it was administered IP, and that means intraperitoneally. The needle is actually inserted into the peritoneum, being careful to avoid touching the uterus, as it was described in this paper, at right angles to the mid-line of the body. So into the peritoneal cavity, in solution, in an oil, into the peritoneum.

Q80 So the Jury will understand, what is the peritoneum?

A It is the body cavity that includes the mesentery, many of the vital organs excluding, of course, the heart and the lung, which is in the thorax. So basically a body cavity including most of the vital organs of the—

Q81 Stomach and the liver.

A The stomach, the intestines, exactly. In answer to your question, the second paper, I believe, they were also administered—no, excuse me. In Exhibit [28] 3 the doses of Aroclor were administered intra—by an intragastric dose, which in toxicology parlance means by gavage, which means basically a needle was put down the throat of the mouse and the material was introduced directly into the stomach, inside the stomach as opposed to the peritoneum which was outside the stomach.

* * * *

[29] Q85 [. . .] Using those terms, can you tell me what the level of exposure was to Mr. Joiner and what dose he got from any evidence anywhere in this case?

A No. I think his exposure to this class of compounds will have to be reconstructed on the basis of his work jobs, the activities that he was involved in on a daily basis, the levels of PCBs in those oils that were drained from transformers, his contact with those, and so forth. If I were asked to do that, what I would try to do is to go back and define tasks and define the time periods with which he was involved in those tasks. I would attempt to learn the levels of halogenated aromatic hydrocarbons in those oils with which he was in direct contact. And very importantly, I would want to know when fires occurred, critically important, when materials were heated. He was a welder I understand. He welded and repaired at times so he [30] brought high temperature in contact with surfaces that were potentially contaminated with PCBs and oils. So of critical importance is on which occasions accidents occurred, during which times high temperatures were applied to "bake out" coils that had been removed, literally dripping with mineral oils and PCBs from these transformers, what sort of ventilation there was in the work space, what sort of protective clothing this gentleman wore, when he was instructed to wear protective clothing, how this protective clothing was disposed of, whether or not he himself and his skin was directly in contact with these liquids. I think a careful analysis of these parameters could lead to a reasonable estimation of his exposure over those years. That would require very careful reconstruction and knowledge of situations.

Q86 Have you been asked to do that?

A No, I have not.

* * * *

[31] Q89 That's a different question than what I asked you. Do you have any information—

A I have heard that—that fires—

Q90 —that he was present when a fire occurred and if so, what is the source of that information?

A Since he repaired transformers, I assumed that he repaired transformers that had been struck, for example,

by lightning. So I would assume that he, until proven otherwise, that he was exposed to by-products of burning and very high temperatures associated with transformer fires.

Q91 Now for him to get any dose from that, what concentrations of PCBs would necessarily be present in the mineral oil, in your opinion?

A Dose is not dependent on the concentration of the PCB in the mineral oil. If there is PCB in the mineral oil, it has the potential to—for him to be exposed to it.

* * * *

[37] Q112 Earlier you testified that you understood that the mineral oil had varying degrees of contamination with PCBs.

[38] A That's correct.

Q113 Can you tell me what the variance was of what—

A No. I don't know what the levels were and I think you should establish that with other witnesses.

* * * *

[Deposition Exhibit 7]

TRIANGLE LABORATORIES OF RTP, INC.
POLYCHLORINATED BIPHENYLS ANALYSIS

File Name: W022015
Concal: W022005
Analyst: VC
Sample Size: 1.00 g
Ical Date: 02/04/92
Spike File: SPPCBC1K
Client: DR. LOUBE
Sample ID: ROBERT JOINER

Analysis Date: 02/05/92
Sample Matrix: ADIPOSE
Sample Origin: n/a
TLI Sample ID: 52-135-1
Project Number: 19710R
Date Received: 12/19/91
Date Collected: / /
Client Project: n/a

Name	Conc (ppt)	[No.]	DL	Empc	Ratio	RT	Flags
2-Mo	ND		26.9				—
44-Di	ND		23.8				—
244-Tr	3870				1.05	21:56	—
2255-T	ND		46.4				—
3344-T	ND		38.4				—
22455-Pe	314				0.59	27:47	—
224455-Hx	56330				1.25	31:51	—
2234455-Hp	36470				1.04	36:18	—
22334455-Octa	9640				0.91	40:31	—
223344556-Nona	5430				0.76	42:13	—
Deca	3070				1.14	43:44	—
TOTAL MONO	ND		26.9				—
TOTAL DI	ND		23.8				—
TOTAL TRI	3870	1			1.05		—
TOTAL TETRA	11680	4			0.79		—
TOTAL PENTA	35410	9		35810	0.68		—
TOTAL HEXA	117440	14		117650	1.24		—
TOTAL HEPTA	84310	13			1.02		—
TOTAL OCTA	35950	5		36220	0.87		—
TOTAL NONA	11200	3			0.78		—

Reviewed By: ———— 2/12/92

PCBC-RPT 4.01, LARS 4.20

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

DECLARATION OF MARK HOMYK

Mark Homyk gives the following declaration in writing subscribed by him, under penalty of perjury, as follows:

1.

He is the Director of Engineering and Electrical Operations for the City of Thomasville Water & Light Department, more than 21 years of age, and competent to give this declaration which is based on his personal knowledge.

2.

Beginning in 1983, the City of Thomasville Water & Light Department began having its mineral oil transformer dielectric fluid in its transformers and voltage regulators tested by independent laboratories to determine whether or not the transformers or voltage regulators were contaminated with PCBs.

3.

The transformers and voltage regulators which were tested by PCBs did not include the entire inventory of transformers of the City of Thomasville Water & Light Department, and the transformers which were tested were, in large part, selected for testing based upon their manufacturer serial numbers which from experience tended to indicate transformers which were possibly contaminated with PCBs, although not always.

4.

To the best of the undersigned's knowledge, the City of Thomasville Water & Light Department never purchased or used any transformers or voltage regulators containing pure Pyranol, pure Inerteen, or similar dielectric fluid mixtures of PCBs.

5.

The computerized information of the City of Thomasville Water & Light Department of PCB test results for mineral oil filled electric equipment, a complete and current printout of which is attached as Exhibit A, is maintained by the undersigned, who is the custodian, and the information is kept in the course of the regularly conducted business of the City of Thomasville Water & Light Department and it was the regular practice of the undersigned to make and maintain the computerized information as a compilation of test results received by the undersigned from time-to-time (as indicated on Exhibit A) from various independent testing laboratories.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 16 November, 1993.

/s/ Mark Homyk
MARK HOMYK

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

Deposition of ROBERT K. JOINER, taken in the above styled case on the 9th day of June, 1993, in the County Commission Room of the Thomas County Courthouse, North Jackson Street, Thomasville, Georgia; commencing at approximately 9:10 a.m., before Judy B. Scott, Certified Court Reporter B-1487, Georgia.

[2] ROBERT K. JOINER,

having first been duly sworn to tell the truth, testified as follows:

* * * *

Q Would you tell us your full name, please.
A Robert Kevin Joiner.
Q Mr. Joiner, how old are you, sir?
A I'm 39.
Q And date of birth?
A 2/9/54.
Q February the 9th, 1954?
A Yes, sir.
Q And where were you born?
A At Thomasville, Archbold Hospital.
Q And have you lived in Thomasville your entire life?
A Yes.
Q Who are your parents?
A Bud and Edna Joiner; both deceased.
Q What was your father's full name?
A Thomas Hall Joiner.

Q And your mother's full name?
A Edna Ophelia Joiner.
Q And when did your father pass?
[3] A November 13th, 1967.
Q And what was the cause of his death?
A A heart attack.
Q What was his age at death?
A Sixty- one. [58]
Q And when did your mother pass?
A Oh, God; '80 or '81, June the 11th of '80 or '81. [6/9/82]
Q What was the cause of her death?
A The final cause was brain cancer.
Q When you say final cause, does that imply that there were some other causes?
A Well, that was what she died of, brain cancer.
Q Were there other diseases that contributed to her death?
A Initially, she had lung cancer; no treatment. The book on that, it normally spreads to your brain. [Had cranial radiation after her cancer had spread to her brain.]
Q And what was her age at death?
A Sixty-one or -two. [64]

* * * *

[4] Q Did your father have cancer, also—
A No.
Q —prior to his heart attack? Any other history of cancer from your grandparents, uncles, or aunts?
A None, either side. [Uncle James mother's brother.]
Q So, your mother was the first member of your family, to your knowledge—
A Right. [No, second.]

* * * *

[18] Q [. . .] And the other two uncles?
A James Bloodsworth.
Q And who?
A And there was Louie Bloodsworth, but he died before I was born.

Q He died at birth?
A No, sir; he was—I don't really know his age. He was a young man, though.
Q And what about James, when did he die?
A In '77, something like that.
Q And do you know the cause of death?
[19] A I'm not sure. [Lung cancer.]
Q And do you know—
A My—
Q Excuse me.
A —Uncle James may have died from cancer. I'm not sure.

* * * *

[20] Q Now, did your father smoke?
A Yes.
Q Did he smoke all the time you knew him?
A Yes.
Q How frequently did he smoke?
A I was young when he died. I—he just smoked.
Q How old were you at his death?
A Twelve.
Q You just knew him to be a smoker?
A Right.
Q How about your mother, did she smoke?
A Yes.
Q And how frequently? A pack a day? Two packs a day?
A I don't know. She just smoked.
Q Would you characterize her as a heavy smoker or moderate?
A Compared to what?
Q To other smokers. You know, like some people smoke ten cigarettes a day, and some people smoke four packs a day. I would say four packs a day is a heavy smoker.
A No, not a heavy smoker.
Q Two packs a day?
[21] A No.

Q A pack a day?
A I would be just guessing—
Q You don't know?
A —and I don't want to do that.
Q No, I'm not asking you to guess. Did she smoke all the time up until the time of her death, that you remember?
A Yes.
Q How old were you when you left her home?
A I'm going slow to get all my facts straight. Twenty-three.

* * * *

[23] Q Did your father smoke cigarettes, a pipe, a cigar or—
A Cigarettes.
Q Cigarettes. Do you know what brand he smoked?
A Pall Mall.
Q Now, what about you, are you a smoker?
A No.
Q Have you ever been a smoker?
A Yes.
Q When did you smoke?
A These dates, you know, you don't write them down on calendars when you start or anything like that. I smoked approximately eight years.
Q When did you start smoking?
A I'm not sure exactly the date. I'm just not sure.
Q Was it in high school?
A I may have played around with them a little bit in high school, but not serious. No; uh-uh (negative response).
Q When do you remember first starting to be a serious smoker?
A I'm not sure. After high school.
Q Do you remember when you quit?
A The fourth Friday in April, 1980 or 1981 [1982]

* * * *

[25] Q So, that would mean you started when you were 18 or 19?

A That's right.

Q What kind of cigarettes did you smoke?

A I smoked some Marlboro, I believe; some Vantage; Salem Lights. [Some Winston.]

* * * *

[29] Q Okay. When you were smoking cigarettes during that eight-year period, how many cigarettes would you smoke on an average day?

A That's hard to judge, but the last two or three years, I would make myself a note or a mental note of if I open a pack at 7:00 a.m., I could not open another pack until the following 7:00 a.m.

Q So, a pack a day the last two or three years?

A A pack every 24 hours; right.

Q What about those first five or six years?

A Probably less.

* * * *

[46] Q Tell us about each job you've had.

A Well, I had the same job all the way through, just more responsibility at it.

Q And a different title, I would assume?

A Yeah. From Apprentice—at that time, they called the next step a "B" Electrician.

[47] Q When did you become a "B" Electrician?

A I'd just have to get the City records to tell you. If I told you, it would be just a pure guess.

Q What was next?

A "A."

Q And you don't know when that happened either?

A Not for—to the year, no. I would be—and then Chief, then brick wall.

Q That's where you are now, Chief?

A (Nodded in the affirmative.)

Q And you've been Chief for how long?

A Seven or eight years, just guessing.

Q When you say brick wall, it means there's no further level for promotion?

A It's hard to say. It's hard; it would be hard.

Q There's no natural progression to go from Chief Electrician to any other position? You're at the top of your category?

A Not without an electrical degree from Tech or somewhere. [. . .]

* * * *

[48] Q Did there come a time when you were a supervisor of other employees of the City?

A I've been a supervisor, a working foreman is what they call me, for a long time.

* * * *

[49] Q Now, when did you take on the supervisory position of working foreman?

* * * *

Q Give me your best estimate. Has it been ten years?

A It's just a guess. Eight or ten.

* * * *

[61] Q [. . .] Could you describe for us your duties at the City of Thomasville, from the time you started [62] in '73 through today. You know, just in a brief narrative, tell us what you've done.

A Transformer repair.

Q You're starting—are you going to start in '73 and come forward?

A Yeah. Like I told you earlier, just more responsibilities were added; nothing changed. Transformer repairs, regulator repairs, substations.

Q Substation repairs?

A Yes. Any electrical work related at the City, repairing lights or stuff. Now, that stopped, but we did all of that, you know, office lights and stuff. Take care of the airport; the peak shaving plant I was talking to you earlier about; motor compressors, motors, motor starters, water softener motors, motor starters.

Q For the Water Department?

A Wells and well starters. Now, that's as-needed repairs; but, our main function was substation and transformer, regulators, and that, you know. Those are our main functions that we do.

* * * *

[65] Q Now, over this period of 20 years, what percentage of your time would you say that you spent working on the repair of transformers?

A And regulators?

Q Well, I want to ask about transformers first.

A Transformers and in the area where they were being worked on?

Q Yes, sir. No, just tell me the time spent working on transformers first.

A Okay. I guess 40 percent or 50 percent of the time anyway.

* * * *

[66] Q So, would you say you spent half your time or 50 to 60 percent of your time doing that work, 40 percent of your time working on these transformers?

A It's hard to say. Probably around fifty-fifty. [50-50 some yrs. then 60-40 some years depending on weather how much time was spent at water softener & gas plant.]

Q Now, of the 50 percent of the time you're working on the transformers, how much of that time would you be working on the changing of the fuel or the oil in the transformer?

[67] A Well, depending on the transformer conditions.

Q Just approximate time, the percentage of your time, though.

A Probably 30 percent; 30 percent of the time. [90% 90%] See, it has to be pumped down before you can see any components in the transformer, to see anything. To inspect it, it has to be pumped. Every transformer—we have to open the top on every transformer that comes in. And if you do any work, you've got to pump it down

to get to it to work. And if you want to untank it, you've got to pump it down to get to the bolts, the attachment bolts, to untank it.

* * * *

[82] Q Now, on the transformers that you have worked on in the shop over this past 20 years, explain to us how you would come into contact with what we call the oil in the transformer.

A By opening the top of the transformer, pumping the oil, doing the repair work.

* * * *

[84] Q In coming in contact with the oil in these transformers, how would you come into contact with it?

A Well, you know, the top won't come off by itself, and you've got to take that off. Then if you want to work on it, you've got to pump some oil out of it. And we'd pump it out with a hose, and then take whatever mechanism we need to take off to work on it. If we wanted to untank it, we untanked it and pumped the oil out.

Q When you had pumped the oil out, where would you put the oil?

A Depending on the situation. If it was a large transformer, clean 55 gallon drums. A small transformer that we thought would take a—would be out of service or be untanked for maybe an hour or two, we might pump it into an open container because it was going back in; but, you didn't want to leave it out a long period, for dielectric—it loses dielectric properties.

* * * *

[94] Q Did the performance of this work require you to [95] come in physical contact with this oil?

A Sure.

Q How would you come in contact with it?

A Now, performance of what part of the work?

Q Any part of it. Just tell us how you would come in—

A Well, you know, if you're working on a transformer all the other years without any protection, no gloves, nothing, you're going to have to pump it out and you've got oil all over you. You're going to have to get in there and untank it. If it's a 500, you just about crawl in it to get in it and unbolt the frame from the tank.

Q So, you get the oil all over you?

A All over you at times. And a hose rupture or spill or all manners of things. You're dropping a tool, and it'd splash up in your face and junk like that. Even the dielectric test, you know, you was there when it was arcing and a little boil of smoke would roll out, you know, when you was testing the oil. It's just you was around—you was just there all the time, really.

Q You said in the early years before they had protective gear?

A Yeah.

Q When did the City furnish you with protective gear?

A This is a guess. I'll have to go back; but, '85 to [96] '87, in that area. [not sure about the date]

Q What did they furnish you with?

A Tyvek suits, Tyvek overshoes, full face respirator and approved filters.

Q And what about gloves?

A And gloves; nitrile PCB gloves or oil gloves, either one.

Q Do you remember when that—why that happened, why all of a sudden you were furnished with this safety gear?

A The EPA started, you know, pushing it, mandating it, and all this.

Q Is that something that other utilities had been using for a long period of time?

A I have no idea.

Q So, all you know is that they said, "Well, here's this protective gear"?

A Right.

Q Were you told to wear it?

A Right.

Q Did you wear it?

A Yes.

Q Always?

A Always, if I knew—now, wait a minute. Let's start over on that. What do you mean by always?

Q Anytime you—

[97] A Anytime I open any transformer?

Q Right; so that you wouldn't come in contact with the oil.

A No.

Q Why would you not wear the gear?

A When I knew—after all the EPA about this PCB's and stuff, when I knew they was non-PCB.

Q How would you know that?

A The only way we'll take a top off a transformer is it—we've got a punch that we punch the side, and we use gloves to retrieve the oil in a bellow and put it in a test vial and ship it off to a certified independent lab for testing. [or if the nameplate on transformer stated no PCBs.]

Q And then it's determined that it is non-PCB?

A Zero parts, then I will not use—I don't use—I won't use it then; but, if it's contaminated or PCB, definitely we've got to have it on.

Q If it had one part per million, then you would wear your protective gear; is that—

A No, I didn't say that. PCB contaminated.

Q If it has more than 50 parts per million?

A Right; right.

Q And you would not—ever since 1985, you have made sure that you wore your protective gear on any transformer that was PCB contaminated?

[98] A That's right; if I knew anything about it, that's right.

Q Or any transformer that would be—

A Suspect.

Q —a PCB transformer?
A Right.

* * * *

[99] Q So, it would be fair to say that since 1985, you've not had any contact with any PCB contaminated oil?
A No, that wouldn't be fair. [Im not sure of date]
Q Why would that not be fair?
A You don't know every transformer, and it's just too many occasions we're around it. We don't—we may not know, and I couldn't say that.
Q But so far as you know, any time that you worked on a PCB contaminated transformer or what might be characterized as a PCB transformer, you wore the gloves, the respirator, the body—
A Whenever we were required to do it, whatever year that was. I'm not sure on the year.
Q Right; we'll have to determine that.
A Okay.
Q But since that time, anytime—
A We try to protect ourselves.
Q Right. So, would it be fair to say that if you have had any contact with a PCB contaminated oil, that that would have to be rare since you've been so careful to make sure that didn't happen?
[100] A Yeah, whenever the date started.

* * * *

[101] Q And you had no knowledge of any reason that that could cause a problem to your health, of any kind, until about 1985 or '87, whatever that date is that we've [102] identified?
A That's correct.
Q And then after that time, you did everything you could to avoid any contact with any PCB contaminated fluid?
A Right.
Q So, I want to talk about prior to and let's—I'm going to use the date '85. I'm not holding you to that—
A I understand.

Q —but that has to be verified. Prior to '85, you made no effort to protect yourself from the contact with this oil in any way?
A No, sir [, but I'm not sure of the date].
Q So, it would come in contact with your skin?
A Yes, sir.
Q Did you ever drink it?
A Drink it?
Q Taste it?
A Well, they might have been a little bit accidentally splash, you know, from tools or something and get in my mouth, and I'd try to get it out; but, as far as drinking, no.
Q Did you ever swallow any of it?
A I have swallowed a little bit of oil, yes.
Q Do you know when you did that?
A No.
[103] Q Have you ever gotten it on your cigarettes and smoked it?
A Now, I just don't know about that. I wouldn't think so.
Q Have you ever gotten it in your eyes?
A Yes.
Q And how has that happened?
A Splashing and then not having eye protection.
Q How many occasions has that happened?
A Several occasions.
Q And what would you do when it was in your eyes?
A Try to get it out the best I could, you know, with water and get it out.
Q Did it burn?
A It burned, and it's very irritating. It's not a burn like alcohol, but it's an irritating burn.
Q Did you every report any incident like that?
A No. I should have I just didn't know the severity of it.

* * * *

[107] Q When were you diagnosed with the lung cancer?

A September '91. [August]

* * * *

[113] Q Now, as I understand it, you had told Dr. Johnson that you had had extensive exposure to toxic fumes and substances containing PCB's. Did you tell him that?

A Yes.

Q And that you had had heavy fume inhalations on several occasions?

A Yes.

Q Some involving fires?

A Yes.

Q Tell us about that, what occasions and—

A Well, we had a couple of transformers and regulator fires. But explaining about the smoke inhalation and all, we bake, what we called "bake-out," transformers that tested low dielectric. We'd untank them and put them on a three-wheel skidder, in the same area we all worked in, and take however many lights it'd take, depending on the size transformer, 1000 watt old ballpark lights and sit them around on step ladders around it and heat it up and get it way above ambient temperature. Smoke would boil off of them and in the same area where we worked. We done that numerous times.

Q Was that smoke just water vapor?

A No.

Q What do you think that was?

[114] A Well, I know it was.

Q What do you know it—

A Oil.

Q You think the oil was boiling off from the stadium lights?

A No, not boiling off. It's just the temperature of the core and coil was so hot that it was smoking. Oil was evaporating or diminishing off of it that way. We'd try

to get—we were trying to get the dielectric strength back up on the transformer core and coils.

Q Was there any heat being applied to the core and coils—

A Yes.

Q —other than the stadium lights?

A No.

Q So, the only heat would be the lights from these stadium lights that would be around the core and the coils?

A Within a foot or two. Those are very hot.

Q But just old stadium lights that came out of an abandoned football field?

A Correct.

Q How many lights would you put around the—

A Depending on the size of the transformer; a minimum of two, up to five.

* * * *

[115] Q So, that's the type fumes you're talking about, the fumes that would be generated by stadium lights mounted on—

A Smoke, yes, and several transformer fires. The tops were blown off.

Q Well, tell me about the transformer fires.

A Well, some of them would blow off the pole. I [116] mean, the tops would blow off; and, we would receive these transformers to work on, all charred and smoking, and breathing that mess.

* * * *

Q How many times did you work on a transformer where the top had blown off?

A It's hard to say. Not an every day occurrence, no; but, it's hard to say.

Q But by the time you got this transformer, there wouldn't be any fumes coming out of it?

A Sometimes not and sometimes, depending on how far that they'd have to deliver it, how long it would take.

Q In other words, you're saying it would be so hot when you opened it that there would be fumes coming out of it?

A Sometimes.

Q How many times did that happen?

[117] A Hard to say; it's some.

Q Would it be so hot that the oil was boiling?

A No. When these tops ruptured and blew off, a lot of times there would be—the oil level would be below the core and coils, and it'd just be smoking when they'd bring it in. Now, that wouldn't happen on an every day occurrence, but it's happened.

Q What about on these fires that you talked about, transformer fires?

A Well, we had a couple of fires in the substations.

Q When were they?

A In the '70s.

Q Where did they happen?

A What do you—

Q What substation?

A Metcalf Avenue is one of them. That was where we had the most problem.

Q Where was the other one?

A That was the main one there.

Q Well, you said there were two.

A A couple of times it happened over there.

Q Oh, two fires at Metcalf Avenue. What caught on fire?

A A regulator, a voltage regulator.

Q So, how would that effect the transformer?

[118] A Well, one time the reactor core faulted, and it shorted and spewed oil and caught on fire.

Q Oil out of the transformer?

A The regulator, the voltage regulator, which was the same manufacturers.

Q What kind of oil is in the voltage regulator?

A The same.

Q Who manufactured that voltage regulator?

A G.E.

Q G.E.?

A Uh-huh (affirmative response).

Q And so you're saying there was some oil that came out of the voltage regulator?

A Uh-huh (affirmative response).

Q And what happened to it?

A Fire.

Q And did you inhale the smoke?

A Yes. We put it out.

Q What other men were out there?

A I was the only one that got real close. There were several others out there. Hogan was in on one of those, but he wasn't real close.

Q What about the other incident?

A We had a main winding—the main winding, off the main winder of the regulator, it's very, very close to the [119] tank initially, and it faulted the ground there and burnt a hole in the side of the tank about two feet off the ground. It's about an eight-foot tank. All that oil run out and it caught on fire.

Q Did you inhale the smoke?

A I did.

Q And whose equipment was that?

A The same.

Q General Electric?

A Yeah. I was required to repair it.

Q Are there any other incidents where you believe that you inhaled fumes from this transformer oil or even the voltage regulator oil?

A Well, the biggest problem, the biggest amount was in the shop baking them out, that smoke.

* * * *

[120] Q Now, as I understand it, your cancer is now in remission?

A It's not evident on an x-ray, on the CAT scan. This is what their words were, "It's so much intensive [121] scarring, we cannot see any obvious at this time."

Q Are you presently undergoing any treatment?
A Not at this time.

* * * *

Q And you're not presently being treated in any way?
A Medication.
Q What type of medication?
A Anxiety; anxiety.
Q But not for the cancer, but for the anxiety?
A. Correct.

* * * *

[129] Q Did you have pneumonia when you were a child?

A I had bronchial pneumonia. I don't remember exactly how old I was, exactly; probably between 10 and 12.

Q Was this—this doctor said you had extensive left pulmonary disease, a major component of which certainly represents post-inflammatory residual from some sort of previous pulmonary disease, such as, pneumonia possibly with emphysema.

[130] A I had pneumonia when I was between 10 and 12.

* * * *

Q In your work place, during these years that you worked on these transformers, how many people in that work area were smokers? You smoked for awhile. How about these other men?

A. Had some; the majority not. I had such a turnover rate.

Q Is that a pretty confined area where you're working?
A It was, yeah.

* * * *

[143] Q Did you ever use any of the oil out of the transformers to start a fire to keep the men warm?

A Unfortunately, several times.

Q How would you do that?

A Take a 20 gallon drum—we had a 20 gallon drum and put oil-dri or anything about eight inches in it and put rags and soak it and light it and burn it.

Q When did you do that? When did that practice occur?

A We done some of that at the airport when it was cold days.

Q When did you discontinue that practice?

A We didn't do it that many times, but we did it; and, I don't know when it—it wasn't from somebody saying stop. It was we just quit doing it.

Q Do you know when?

[144] A No, sir.

Q This happened in the '70s or—

A Oh, yes. It definitely—it happened—I wouldn't have lit that up and done that knowing—after I quit smoking, I wouldn't have done that.

Q In 1980 or '81?
A Correct.

Q And that was because you just didn't want to inhale any smoke?

A That's correct.

* * * *

[145] Q Now, you said in your Answers to Interrogatories that you smoked Winstons. You said earlier this morning you smoked Marlboro. Which was it?

A Well, it's—I thought about that. It was some of both, but I wasn't a regular on either one of them; but, that was—some of both.

Q So, Winstons, Marlboros, Vantage, and Salem Lights?
A Correct.

* * * *

[183] Q [. . .] Now, I want to make sure I understood [184] this. To your knowledge, did the Water and Light Department ever purchase any transformers that contained Askerel dielectric fluid; or, were they all mineral oil transformers, to your knowledge?

A Not to my knowledge, they didn't, not to my knowledge.

Q When you say not to your knowledge—

A Because I wasn't over purchasing.

Q When you say not to your knowledge, do you mean—it's sort of a double negative there. To your knowledge, they never purchased an Askerel transformer; is that correct?

A To my knowledge.

* * * *

[195] Q So, it's on a three-wheel skidder. Was the purpose of baking the core to get the moisture out of the core so that you'd get your dielectric up?

A Correct.

Q It wasn't to boil the mineral oil off; it was to get the water out, the moisture?

A Well, you couldn't boil it out, anyway. You'd have to dry—you'd have to get a temperature well above ambient to dry it out, though, or you'd be there for months. You have to really heat it up, in my working with it.

* * * *

[197] Q When those were being baked, what would you be doing during that time; just going about your other responsibilities?

A Yes, sir; in the shop, repairing those, repairing other tools. We repair all the tools and all. Ordering; I'm responsible for ordering all the electrical equipment. My desk was about 50 feet from where the bake-out was.

Q Would you have also, during that time, have been going to the—let's see here—airport or the other places that you had to go?

A That's possible.

Q Now, when the steam would rise off of these cores—

A It's smoke.

Q —or smoke would come off of those cores, did it ever burn your eyes?

A Yeah; it could be very irritating if you—you know, you had to just be careful.

Q I mean, did you try to stay away from it when it was being baked?

A Well, there wasn't a whole lot I could do, if I had to work in that shop. And what was the worse is leaving the lights on and letting the door down for the weekend and let them continue to boil until you got back and all that smoke [198] was everywhere, and we done that.

* * * *

[199] Q But when you weren't baking spares to keep your spare inventory up, then you said you might go a long time without having to bake one?

A You may go a couple of months maybe without baking one.

Q What's the longest you think you ever went between baking cores?

A I really don't—I couldn't say for sure and be accurate.

Q Do you have any recollection of how many that you ever baked consecutively, one right after the other; any recollection of that?

A No.

* * * *

[204] And I take it the purpose for drying the core is you want to be able to use it when you get through, put it back in the transformer?

[205] A Correct.

* * * *

[206] Q Now, you mentioned two fires of voltage regulators. Do you remember any other fires involving any transformers, either pad mounted or pole type?

A Yes; we had several pole mounted transformer fires.

Q Do you recall whether you were involved in extinguishing any of those?

A I was not involved in extinguishing those.

* * * *

[207] MR. COCHRAN: Let's get the Court Reporter just to mark that as Joiner Exhibit Number 1, please, ma'am.

(Whereupon, Court Reporter marked exhibit as Joiner Exhibit 1 for identification.)

Q Take a look, if you would, Mr. Joiner. That's a document that you were kind enough to produce for us in this lawsuit. Is that a report that was kept by the Water and Light Department on one fire, where you went to the scene after the fire?

A Correct.

Q And the fire itself was extinguished by the fire department, was it not?

A They were sent to the area, but they didn't put the fire out.

Q Because the rain did; is that right?

[208] A Correct.

Q This occured in what year?

A '88.

Q So, this would have been after you were wearing protective gear?

A It was a late evening call out. Sometimes we didn't even know what the problem was until we got there, and we did not have the protective gear on our truck, the vehicle. All of this was in the shop. This is most of the—most of this kind of PCB work was lined-up, scheduled work; and, these were emergency situations, and we did not have it on the truck in every case, no.

Q Do you know whether you had it for this particular incident?

A I did not.

Q But in this particular incident, the only dielectric fluid that caught fire only had 26 parts per million?

A Correct.

Q And by the time you got there, the fire was already out?

A It was still smoking terribly, and it—but the fire itself was out; correct.

Q This says, "Rubber boots, gloves, plastic suits, brooms were placed in the DOT drums." What were those?

[209] A That's after the clean-up the following day.

Q How long were you there the evening?

A About 45 minutes.

Q What did you do while you were there?

A Went into the station and made sure everything was—all of the fuses were pulled, checked the transformer status, and set the top back on the transformer. It was scalding hot.

* * * *

[210] Q Did Dr. Shecter physically examine you?

A When you say physically exam, put his hands on me and—

Q (Nodded in the affirmative.)

A No.

* * * *

Q Where did you meet with Dr. Shecter?

A Where did I—

[211] Where?

A Did I meet him?

Q Yes. In Atlanta, where?

A At my lawyer's office.

Q That'd be Mr. Warshauer; right?

A Yes, sir.

* * * *

[213] Q [. . .] How many times have you met with Dr. Shecter?

A One time.

Q Now, when you met with him, was anyone present other than Mr. Warshauer?

A I believe all the other lawyers here were there. I believe they were.

Q Was your wife there?
A Yes.
Q Anyone else?
A There was a—I don't know what her position was.
Q Somebody that worked for Mr. Warshauer?
A Correct.
Q Anybody else?
A No, sir.

• • • •

[214] Q Now, you mentioned that your Uncle James had died of some form of cancer, but you weren't sure what it was. Did you have a second uncle who also died of cancer?

A That—Uncle James died of cancer.

Q Right. Was there another one, other than the Uncle James?

A No.

Q And you don't know what form of cancer that was?

A I can find out. [lung cancer]

• • • •

[223] Q What was the primary site of your mother's cancer?

A Initially?

Q Yes, sir.

A Lung cancer.

• • • •

[226] Q Now, when you were seen by Dr. Shecter—let's turn to Dr. Shecter for a minute. Did he prescribe any treatment for you? I mean, was he going to treat you in any way?

A Not at this time.

Q Was there any suggestion that he might treat you in the future?

A No.

• • • •

[231] Q Do you know of any other utility that would take cores out and bake them by clamping old stadium lights on step ladders?

A I don't. I don't know of any that did. I'm not saying they didn't.

Q You've never talked to any other utility about doing that?

A No.

Q Do you know who came up with the idea to do that?

A No.

Q Do you know how long they had been doing that at [232] the Water and Light Department before you got here?

A No.

• • • •

[Exhibit Joiner #1]

10 JUL. 88

(ASSUMED PCB CONTAMINATED) SPILL REPORT
LOCATION: CITY OF THOMASVILLE PEAK SHAVING PLANT LOCATED ON PINETREE BLVD WEST OF THE OLD ALBANY RD

DETAILS

DURING THE LATE EVENING OF 27JUN88 LIGHTNING STRUCK THE ELECTRICAL SYSTEM FEEDING A PAD MOUNTED TRANSFORMER BANK CONSISTING OF 4 TRANSFORMERS. THE WIRES, TRANSFORMERS, ETC. SHORTED OUT CAUSING A SMALL FIRE ON THE CONCRETED PAD. THE TOP OF ONE OF THE TRANSFORMERS HAD COME LOOSE DUE TO THE BUILD UP OF INTERNAL PRESSURED FROM THE ELECTRICAL FAULT AND SOME OF THE OIL HAD BOILED OVER THE TOP OF THE TRANSFORMER AND SOME OF THIS OIL CAUGHT ON FIRE AND BURNED. PROBABLY BETWEEN 20 AND 30 GALS OF OIL WAS GONE FROM THE TRANSFORMER. THE FIRE DEPARTMENT WAS SENT TO THE AREA, BUT THE RAIN WAS FALLING AT SUCH A FAST RATE THAT IT EXTINGUISHED THE FIRE. ROBERT JOINER (CHIEF SUBSTATION ELECTRICIAN) WAS CALLED TO ACCESS THE DAMAGE AND DETERMINE THE PCB LEVELS OF FLUID WHICH HAD ESCAPED CONTAINMENT. THE DEXSIL SCREENING TEST WAS PERFORMED ON ALL 4 TRANSFORMERS WHICH WERE AT THIS LOCATION AND THE TEST INDICATED THAT 3 OF THEM MIGHT BE CONTAMINATED WITH PCBS. LAB SAMPLES WERE TAKEN AND SENT FOR QUICK VERIFICATION TO " PPM ".

ON 28JUN88 THE MAIN PORTION OF THE CLEANUP OPERATION BEGAN. ALL EXPOSED WIRE, BROKEN BUSHINGS ETC. WERE PLACED IN DOT OPEN HEAD DRUMS. WHEN THE MISC. DEBRIS WAS REMOVED FROM THE AREA. WIPE SAMPLES WERE TAKEN ON THE CONCRETED PAD AND SOIL SAMPLES FROM THE AREA AROUND THE PAD. THE PAD WAS THEN CLEANED AND THE SOIL AROUND THE PAD DUG UP AND PLACED IN DRUMS. AFTER CLEANUP SAMPLES WERE TAKEN THEN FROM THE SOIL AND PAD. RUBBER BOOTS, GLOVES, PLASTIC SUITS, BROOMS WERE PLACED IN THE DOT DRUMS. THE FOLLOWING IS A LIST OF INDIVIDUALS WHO PARTICIPATED IN THE CLEANUP.

ROBERT JOINER
RALPH HOGAN
DAVID FOGLE
RONNIE PRANCE
ROBERT BURGESS
JAMES ADCOCH
JOE BATTLE
TIM WEAVER
MARK HOMYK
JOHNNY EDWARDS
FLOYDZELL SAMPSON

THE FOLLOWING IS A LIST OF THE TRANSFOMERS WHICH WERE LOCATED AT PEAK SHAVING PLANT

TX NO	MFG.	SERIAL NO	KVA	DEXSIL TEST	OFFICIAL LAB TEST
**2812	GE	H292457P70AA	167	GT50	26 PPM
1576	GE	C64941857P	167	GT50	287 PPM
1578	GE	C649006569	167	GT50	292 PPM
2822	GE	K175365Y71AA	25	LT50	

ON THE 28JUN88 TOM BERRY ACTING WATER & LIGHT DEPT. SUPERINTENDENT NOTIFIED THE DNR (SCOTT BALES ERT DIV OFFICER) AND THE NATIONAL RESPONSE CTR (TROUSDELL) WHO ASSIGNED THE #8636 TO THE INCIDENT.

LATE FRIDAY EVENING (1JULY88), I WAS NOTIFIED BY " PPM " OF THE RESULTS OF THE PCB TEST.

ON THE 5JULY88 I NOTIFIED THE OFFICE OF THE ERT DIV OFFICER AND THE NATIONAL RESPONSE CTR OF THE LAB TEST.

** WAS THE ONLY TRANSFORMER FROM WHICH ANY MATERIAL SPILLED OR BURNED DURING THE ABOVE DESCRIBED INCIDENT.

MARK W. HOMYK
Distribution Engineer

[Deposition Exhibit 5]

AFFIDAVIT OF ROBERT JOINER

Personally appeared before me, the undersigned officer duly authorized to administer oaths, Robert Joiner, who after being duly sworn deposes as follows:

1.

I am Robert Joiner, a competent adult. I am 37 years old and was born on February 9, 1954. I make this Affidavit for any lawful use or purpose.

2.

I have personal knowledge of the facts set forth in this Affidavit.

3.

I have been an employee of the Thomasville Electrical Cooperative since the Summer of 1973. At that time my position was classified as Apprentice: Substation, Electrical. My duties included repairing, cleaning and maintaining electrical transformers, oil testing, regulator repairs, and line repair items. In 1975 or 1976, I was promoted to Foreman; a position I held until the onset of my disability in August of 1991. As Foreman, my duties were expanded to include those of electrical repairman for the airport and primary/SECC underground cable repairman.

4.

Throughout the course of my employment with Thomasville Electrical Operative I was routinely exposed to Polychlorinated Biphenyls or, PCBs. The nature of my work caused me to inhale PCB fumes and endure the absorption of PCBs through my skin. The PCBs were contained in dielectric oils used in electrical transformers manufactured by General Electric and Westinghouse Electric.

5.

I inhaled PCBs while performing repair and maintenance work on transformers, as well as during instances of fire.

A.) On occasion I was required to repair large transformers. Once the oil containing PCBs was be drained, I would enter the transformer to make the necessary repairs. The transformer's inside casing usually continued to drip oil during the repair process, and oil also accumulated at the base of the transformer. I normally placed cardboard beneath me to avoid having to lay or sit in, the oil while working. The area in which I worked was almost completely enclosed, with the only vent hole being approximately 18 inches wide. The work space was very confined and extremely hot. My tasks usually required several hours work, during which I continuously breathed oil fumes laden with PCBs.

B.) Smaller transformers were delivered to and repaired at, the shop. The repair work required me to drain the transformer cases of oil and then, in the enclosed shop, heat the transformer cases under heat lamps to dry them out. During this process, the vapor from the oil containing PCBs filled the shop, and I inhaled it for many hours at a time.

C.) I often repaired transformers that had varying degrees of insulation contamination or, break-down. In these instances, the transformer's coils were untanked and placed under (four) 1500-Watt field lights in order to remove moisture from the winding. During the drying process, the transformer core and coils became so hot as to emit large quantities of smoke and fumes. The transformers were "baked" for seven or eight day periods, during which I was forced to work in the smoke-filled shop and inhale the PCB fumes.

D.) The most serious cases of insulation contamination/breakdown resulted in fire or, explosion of the transformer, both of which caused me to inhale concentrated fumes containing PCBs.

E.) I also inhaled PCB laden fumes while doing repair work from atop the transformer through the hand hole cover. I recall a particular emergency repair on a secondary connection, wherein the transformer's extreme temperature forced me to lay on cardboard connection, wherein the transformer's extreme temperature forced me to lay on cardboard while working. The PCB containing oil was so hot it had to be pumped down, and the combined heat sources caused fumes to rise. Since I was positioned on top of the transformer, I was forced to breathe the PCB fumes for the duration of the repair work—approximately four hours.

6.

The absorption of PCBs through my skin occurred during repair tasks, oil testing, and the " "untanking" " of transformers.

A.) The repair of small transformers involved submerging my hands and forearms in the chemical liquid contained inside the transformer case. In order to manipulate windings, I had to extend my hand down through the hand hole into the case. Other repairs required removing the top of the transformer and pulling out the inner core; whereupon, the PCB containing oil was allowed to drip into a pan before the core was serviced. Both repair methods involved skin contact with the oil containing PCBs; and often times, this chemical liquid splattered onto my clothing.

B.) Due to valve malfunctions, I was occasionally sprayed with oil containing PCBs while collecting samples for oil testing. At times the oil samples themselves spilled onto my hands, clothing, or shoes during transport.

C.) Prior to 1983, I was involved in the " "untanking" " (drainage) of large transformers. This process

often lent itself to accidental spillage, gushing valves, and random dumping of the chemical liquid. Upon completion of the " "untanking" ", my clothes, hands, and shoes were often covered with oil containing PCBs.

7.

During the period 1973 through 1983, I was unaware of the harmful effects of PCBs. The manufacturers of the transformers did not advise me of precautionary handling methods, nor was protective clothing or equipment recommended to me. The transformers upon which I worked bore no warnings or hazard signs concernings PCBs.

8.

I was not exposed to PCBs outside of my employment with Thomasville Electrical Cooperative.

9.

In August of 1991, I was diagnosed as suffering from squamous cell carcinoma (a form of lung cancer). This disease resulted from my occupational exposure to PCBs.

/s/ Robert Joiner
ROBERT JOINER

Sworn to and subscribed before me this 26th day of December, 1991.

/s/ [Illegible]

Notary Public, Thomas County, Georgia
My Commission Expires August 20, 1994

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

The deposition of DR. PHILIP COLE, taken pursuant to Notice and agreement for cross-examination, discovery and any other purpose allowed by law and pursuant to the Federal Rules of Civil Procedure and the Federal Rules of Evidence; all formalities waived, excluding the reading and signing of the deposition; before Joyce S. Oglesby, Certified Court Reporter and Notary Public in and for the State of Georgia; commencing at 12:10 p.m., Thursday, October 21, 1993 at 4000 One Peachtree Center, 303 Peachtree Street, Atlanta, Georgia.

* * * *

[5] DR. PHILIP COLE

was called as a witness herein and, having been first duly sworn, was examined and deposed as follows:

* * * *

[10] Q. This next document I'm handing you is Plaintiffs' Exhibit No. 4. It's captioned "Smoking and Small Cell Lung Cancer." What is this?

A. This is a document that was prepared by me in August of this year, and it relates to what I consider to be a few of the salient aspects of that disease, that is small cell lung cancer.

* * * *

[24] A. So, I understand the question to be, if I may rephrase it: Is it true that you now hold the position that PCBs could not be a cause or a contributing factor in this particular case?

Q. Correct.

A. Okay. My response to that is that I would not make a statement that was as absolute as that question calls for, but I would say that in my judgment it is virtually certain that it was not a cause in this case.

Q. Or a contributing factor?

A. Well, I thought we'd been over that and had [25] agreed that cause and contributing factor were synonymously referred to as cause.

* * * *

[46] Q. Dr. Cole, are you aware of any harmful effects of PCBs on human beings? And I'm talking for purposes of this question short of an acute dose that would cause injury within a very short period of time.

[47] A. I'm not real sure of this, but I think that under some circumstances they can cause dermatitis or an inflammatory reaction of the skin, but apart from that, I—I'm not aware of any adverse health effect.

Q. How about of polychlorinated dibenzofurans?

A. I—I don't know.

Q. How about of polychlorinated dibenzodioxins?

A. With regard to the furans, I guess in high dose they do cause acute—an acute syndrome, sometimes called Yusho disease, Yu-Cheng disease. I—I really don't know exactly what the components of that are. As far as the polychlorinated dibenzodioxins are concerned, some of them, at least one of them, is—is quite a potent poison.

Q. With respect to the furans, you mentioned that you're aware of the acute effects, which you've described as—I guess referring to the Yusho or rice oil poisoning. And the longer term, more chronic effects, are you aware of any of those?

A. No.

Q. And of the PCBs, except for the dermatitis which you described, are you aware of any long-term problems that have been associated with PCBs?

A. No, I'm not.

Q. And with respect to the dioxins, you [48] mentioned that at least one of the congeners of dioxin is poisonous or acutely poisonous. I can't remember your exact word.

A. Well, —

Q. Are you aware of any long-term problems associated with dioxins?

A. Long term in the sense that it persists, but short term in the sense that it has a relatively short induction period with the chloracne.

* * * *

[49] A. I only meant to say that with regard to the question, "Are there diseases caused by these classes of chemicals and which make their clinical appearance after a long induction period?" my answer was, "I do not have a response to that. I do not know."

Q. Let me make sure that I've covered the waterfront on these chemicals. Are you aware of any disease processes that may begin shortly or immediately [50] following exposure but have a long life themselves?

A. The answer to this question is yes. Those conditions are chloracne and some of the signs and symptoms of the disease complex known as Yusho or Yu-Cheng, and those are the—those are the only ones that I'm aware of.

* * * *

A. And the question is: Is there any cancer in human beings that is known to be caused or promoted by PCBs?

Q. Yes.

A. No.

Q. How about dioxins, the same question?

A. My position is that no human cancer is caused or promoted by dioxins, but I do understand that this is an area of some controversy.

[51] Q. By your use of the last phrase "this is an area of some controversy" in your response to the dioxin question and your failure to use a similar phrase in response

to the question concerning PCBs, am I to assume that it's your position that there is no controversy concerning carcinogenic properties of PCBs?

A. With the understanding that one or two people won't make a controversy, the answer would be yes.

Q. Do you agree that there are at least some scientists who appear to be adequately trained who believe that PCBs do contribute to certain kinds of cancers in humans, sir?

A. I don't doubt that there is such a person or some number of people, but I couldn't name one for you. I really don't—I don't know of any.

Q. Looking at your Curriculum Vitae, in the teaching aspect of it, page 3, at the University of Alabama in Birmingham, is that where you presently are employed?

A. Yes.

Q. It says that you have taught epidemiology of cancer there?

A. Yes.

Q. The principles of epidemiology research?

A. Correct.

[52] Q. Advanced epidemiologic methods?

A. Correct.

Q. And that you've put on a doctoral seminar?

A. Correct.

Q. And those are also in the epidemiologic field?

A. Yes.

Q. Do you train people in your program to follow the correct methods of epidemiological science?

A. Of course.

* * * *

[56] Q. How many people does it take or what percentage of the scientific community in a particular field of study must hold the opinion for it to be recognized?

A. I can't—I can't answer that, except to point out to you that generally scientists don't divide themselves 50/50 on a—on a question, except in the earliest phases of it, that it then moves to 95/5 or 5/95. So, as long

as we're in the area where people are not taking positions, then it's a cause/effect relationship that is, in my parlance, not recognized.

Q. The bottom line of our last few questions, I guess, other than those concerning methodology or definitions of words, I want to make sure I understand, it's you opinion from your readings that there are no cancers in humans recognized as having been caused by exposure to PCBs?

A. That is correct.

Q. But do you agree that there are at least some scientists who hold the opinion that there is a correlation between PCBs and certain cancers?

A. Now, you've not only changed—

[57] Q. Oh, I have changed—

A. —the question from my view to what I think scientists, but you've also changed cause to correlation.

Q. Okay. Well, stay with cause, and then we'll go to correlation.

A. The question is: Do I recognize that there are credible scientists who hold the view that PCBs are an established human carcinogen?

Q. Yes.

A. The answer is that I cannot deny that there are such people, but I don't know who they are. I can't name anyone for you.

* * * *

[74] Q. We talked about benzene as a chemical of which you're aware is a human carcinogen for certain organs. Are you aware of any other chemicals which you recognize as human carcinogens?

A. Well, firstly, I did not acknowledge benzene to be a human carcinogen for certain organs.

Q. Okay. You gave me a disease, and I apologize for misstating that.

A. Okay. Now, you're asking me am I aware of any other chemical which is a recognized human carcinogen?

Q. Yes, sir.
A. Okay. The answer is yes.
Q. What are those?
A. There is a list of these compounds that I would be pretty willing to subscribe to, but I'll—I'll answer your question from my memory.

We've already mentioned benzene, Diethylstilbestrol, beta naphthylamine, 4-aminopbiphenyl, aflatoxin, bischloromethyl ether.

* * * *

[75] Q. Where would you—
A. Was there a favorite one of yours that you'd like me to agree to?
Q. You mentioned that there's a list. Where would I go to find a list that you would recognize? I know you just work from memory, and you may have inadvertently included one that's not on the list or included one—failed to include one that is on the list. I accept that as a possibility. Where would I go to find a list that you would recognize?
A. First, let me tell you that I didn't mention one that would not be on the list.
Q. Okay.
A. But I certainly did fail to mention some that—that are on the list.

The list that I like best, which is not to say that I subscribe to it across the board, is the list of Class I carcinogens put forward by the International Agency for Research on Cancer.
Q. IARC?
A. Correct.
Q. Do you recognize that group as a group that [76] is—whose opinions on cancer should be given a certain amount of credibility?
A. Let me say that there is no such thing as that group. The IARC is, in the context of which we're speaking, a convening body. It is not a authoritative body in and of itself. So, if I change your—if I change your question to be, "Are the results of the workshop

groups convened by the IARC generally to be accredited?" the answer's yes, generally.
Q. Can you think of specific examples which you do not give credit to?
A. Sure, I'll be glad to give you one.
Q. Okay.
A. They—This does not pertain however to Class I carcinogens, but to Class II. They consider, as an example, formaldehyde to be a Class II-A carcinogen. I would put it as a Class II-B. The same could be said for butadine. Those are two examples.

* * * *

[78] Q. No, I don't, but I would like to know how you believe those principles are applicable to your opinions that PCBs didn't have anything to do with Mr. Joiner's lung cancer.
A. Let me give you the short answer and see if that suffices. I think that that statement was intended to imply that there is a body of epidemiologic information that speaks to that question. That body of information includes about eight or so studies, that each of those studies can be evaluated individually, that the body of information that they comprise can be evaluated collectively, and that from those evaluations in the context of a set of criteria for making interpretations from individual studies and for making an interpretation from a body of knowledge collectively, one can deduce that PCBs have been shown not to cause cancer of the lung in human beings and that, therefore, they could not have caused Mr. Joiner's disease and furthermore, from the larger set of criteria that Mr. Joiner had an alternative cause of lung cancer which he experienced and that as a result of those two propositions, it is a virtual certainty that Mr. Joiner's disease was caused by his [79] cigarette smoking and that his occupational exposures contributed nothing to this.

* * * *

[87] Q. Well, from the studies you've read and your research into this area, do you think or do you believe

that there's any need to do any more research in the area or has it been established to your satisfaction as a scientist that these things are never going to be shown to be human carcinogens?

A. The context of your question of whether or not any more research is needed is from the specific point of view of showing them conclusively to be or not to be human carcinogens?

Q. Yeah.

A. Mr. Warshauer, I don't want to speak to that because conclusiveness in the sense in which would mean that almost everybody holds only one point of view is something a little difficult to achieve.

Q. Well, it's been achieved in cigarette smoking?

A. Yes, it has.

Q. Has it been achieved in benzene?

A. Well, now, wait a minute. You're talking about carcinogens. Here, we're talking about something that is virtually certainly not a carcinogen. So, the—the burden of proof for showing the absence of an effect [88] is substantially greater than that for showing no effect when you speak about the broad scientific community. So, if you ask me the question do I believe that the evidence is—is clear on PCBs and human carcinogenesis, I can't answer that, but what it will take to whip everyone into line, I don't—I don't know.

Q. In other words, people who are still studying it have reason to continue to study it because there are indeed people who aren't, quote, whipped into line?

A. Mr. Warshauer, I don't know why someone would choose to do yet another study of PCB carcinogenesis. All I can tell you is that I would not. I think it so unlikely to be rewarding that I don't want to spend a significant portion of the remainder of my career running up that alley. Here, you have a body of evidence that doesn't give the slightest inkling that these things cause human cancer. If—Surely if they were human carcinogens, we would see some evidence of it here (indicating), and we don't.

* * * *

[113] Q. Does one's risk of lung cancer diminish after one ceases smoking cigarettes?

A. The answer to that is probably yes, but that's not quite so clear in the form of lung cancer that he had, and also in any case probably doesn't happen to any appreciable extent for 10 or so years subsequent to cessation.

Q. Does it happen to an appreciable degree in seven or eight years?

A. Probably not, especially for small cell.

Q. What is unique about the small cell aspect of this case?

A. The literature on small cell suggests that the reduction in risk subsequent to cessation occurs more slowly, but admittedly, this is not a firm conclusion.

* * * *

[114] Q. Now, Mr. Warshauer also identified Plaintiffs' Exhibit No. 4, which is entitled "Smoking and Small Cell Lung Cancer," and I notice that on the first page of this, it has a heading "Association with smoking," and then it talks about, and let me just quote [115] this. It says, "SCLC," which I assume is an abbreviation for small cell lung cancer, "is strongly associated with smoking. Estimates of the relative risk," and then in parentheses it has "odds ratio varies from 5.0," a dash, "42.5 for current smokers."

What does that mean?

A. This means that the literature says that current smokers, and by implication, really ever smokers, have a risk of—Indeed SCLC stands for small cell lung cancer. —that is increased anywhere from five fold to about forty fold or the SMR terms that we were using before is anywhere from five hundred to four thousand or two hundred or so. In other words, there's a massive association between SCLC and cigarette smoking.

* * * *

[Plaintiff's Exhibit 1]

CURRICULUM VITAE

Born: August 22, 1938
Boston MA

Name:

Philip Cole

Position:

Professor and Chairman
Department of Epidemiology
School of Public Health
-and-
Associate Director for Epidemiology
Comprehensive Cancer Center
University of Alabama at Birmingham

Address:

Department of Epidemiology
School of Public Health
Room 203, Tidwell Hall
UAB Station
Birmingham, Alabama 35294

Telephone:

(205) 934-6707

Fax:

(205) 934-8665

Education:

Michigan State University	B.A.	1960
University of Vermont	M.D.	1965
Harvard University	M.P.H.	1967
Harvard University	Dr.P.H.	1970

Previous positions:

Department of Epidemiology Harvard School of Public Health	
Assistant and Associate Professor	1969-78
Professor	1978-79

Consultant in Epidemiology and Biostatistics Unit of Epidemiology International Agency for Research on Cancer	1977-78
Surgical Intern, Royal Victoria Montreal Hospital	1965-66

Certification and Professional Societies:

Licensed, Alabama Medical Licensure Commission	1981
Member, American Epidemiologic Society	1973-79
Certified, American Board of Preventive Medicine	1971
Licensed, Board of Registration in Medicine, Commonwealth of Massachusetts	1966-1980
Diplomate, National Board of Medical Examiners	1966

Honors:

American Cancer Society, Faculty Research Award	1973-78
Merk Lecturer, Montreal Cancer Institute	1977
Gordon Richards Memorial Lecturer, Ontario Cancer Treatment and Research Foundation	1979
John Whittick Memorial Lecturer Canadian Cancer Society	1980
Kammer Merit in Authorship Award American Occupational Medical Association	1982

John Rankin Visiting Professor of Occupational and Preventive Medicine
University of Wisconsin, Madison 1983

Eleanor Leader Memorial Lecturer
University of Toronto, Toronto 1985

Grand Prix Lacassagne du La Ligue Nationale Francaise contre le Cancer (with B. MacMahon, J. Brown and D. Trichopoulos) 1986

First Annual President's Award Outstanding Teacher
University of Alabama at Birmingham 1991

Major Committees:

Scientific Advisory Committee
Division of Cancer Cause and Prevention
National Cancer Institute 1978-80

Epidemiology and Disease Control Study Section
National Institutes of Health 1973-77

Clinical and Epidemiological Research Advisory Group
National Cancer Institute of Canada 1973

Committee on Epidemiology and Prevention (Chairman)
National Bladder Cancer Project
National Cancer Institute 1971-73

General Motors-United Auto Workers Occupational Health Advisory Board 1982-87

Mott Prize Selection Committee
General Motors Cancer Research Foundation 1985

Prevention, Cancer Control (Chairman) Steering Committee for the National Planning Effort
National Cancer Institute 1984-85

Board of Scientific Counselors
Division of Cancer Prevention and Control
National Cancer Institute 1986-90

Scientific Advisory Committee
Pittsburgh Cancer Institute 1987-89

Advisory Council on Epidemiology
Electric Power Research Institute 1986-90

Teaching:

Harvard School of Public Health
The epidemiology of chronic diseases 1969-72
The epidemiology of neoplastic diseases 1973-77
Epidemiologic methods 1976
Principles of epidemiology 1978-79

University of Minnesota—Graduate Summer Session
The epidemiology of cancer 1971, 74-80
Principles of epidemiologic research 1985
Fundamentals of epidemiology 1986, 87

International Agency for Research on Cancer
Cancer epidemiology 1974, 76, 78, 80

University of Massachusetts-Graduate Summer Session
Principles of epidemiology 1981-84
Cancer epidemiology 1982

Tufts University—Graduate Summer Session
Epidemiologic bases of public health policy and law 1986, 87

University of Alabama at Birmingham
Epidemiology of cancer 1980

Principles of epidemiologic research 1980-91

Advanced epidemiologic methods 1981

Doctoral seminar 1981-91

University of Michigan—
Graduate Summer Session
Principles of epidemiology 1989-91

Research Interests:

The epidemiology of breast cancer,
Hodgkin's disease and bladder cancer
Health effects of exogenous hormones
Occupational and chemical carcinogenesis
Health effects of electromagnetic fields

Editorships:

Associate Editor, Cancer Research 1982-85

Associate Editor, American Journal
of Epidemiology 1982-88

Editorial Board, International Journal of
Breast and Mammary Pathology 1984-

Editorial Board, Fundamental and
Applied Toxicology 1984-

Editorial Board, Southern Medical Journal 1990-

Publications: See attached list.

Prepared: January 2, 1992

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1. Cole P, MacMahon B, Aisenberg A: Mortality from Hodgkin's disease in the United States: evidence for the multiple-aetiology hypothesis. *Lancet* 2:1371-1376, 1968.
2. Cole P, Gutelius J: Paraplegia resulting from the use of the subclavian artery as a shunt source during resection of the descending thoracic aorta. *Ann Surg* 169:293-294, 1969.
3. Rapoport A, Cole P, Mason J: Correlates of survival after initiation of chemotherapy in 142 cases of Hodgkin's disease. *Cancer* 24:377-381, 1969.
4. Cole P, MacMahon B: OEstrogen fractions during early reproductive life in the aetiology of breast cancer. *Lancet* 1:604-606, 1969.
5. MacMahon B, Cole P: Endocrinology and epidemiology of breast cancer. *Cancer* 24:1146-1150, 1969.
6. Cole P, Gutelius J: Neurologic complications of surgery on the descending thoracic aorta. *Can J Surg* 12:435-443, 1969.
7. Kaplan S, Cole P: Factors affecting response to postal questionnaires. *Br J Prev Soc Med* 24:245-247, 1970.
8. MacMahon B, Cole P, Lin TM, et al.: Age at first birth and breast cancer risk. *Bull WHO* 43:209-221, 1970.
9. Cole P, Monson RR, Haning H, Friedel GH: Smoking and cancer of the lower urinary tract. *N Engl J Med* 284:129-134, 1971.
10. Mirra A, Cole P, MacMahon B: Breast cancer in an area of high parity: Sao Paulo, Brazil. *Cancer Res* 31:77-83, 1971. Reprinted in Portuguese in *Rev Assoc Med Bras* 18:357-364, 1972.

11. Cole P: Coffee-drinking and cancer of the lower urinary tract. *Lancet* 1:1335-1337, 1971.

12. MacMahon B, Cole P, Brown JB, et al.: OEstrogen profiles of Asian and North American women. *Lancet* 2:900-902, 1971.

13. Hoover R, Cole P: Population trends in cigarette smoking and bladder cancer. *Am J Epidemiol* 94:409-418, 1971.

14. Cole P, MacMahon B: Attributable risk percent in case-control studies. *Br J Prev Soc Med* 25:242-244, 1971.

15. Allen DW, Cole P: Viruses and human cancer. *N Engl J Med* 286:70-82, 1972. Reprinted in *Ca—Cancer Journal for Clinicians* 23:127-136, 1973 and in *Diagnostic* 4:189-194, 1973.

16. Trichopoulos D, MacMahon B, Cole P: Menopause and breast cancer risk. *J Natl Cancer Inst* 48:605-613, 1972.

17. Cole P, Hoover R, Friedell GH: Occupation and cancer of the lower urinary tract. *Cancer* 29:1250-1260, 1972.

18. MacMahon B. Cole P: The ovarian etiology of human breast cancer. *Current Problems in the Epidemiology of Cancer, Lymphomas and Leukemias. Recent Results Cancer Res* 39:185-192, 1972.

19. Cole P: Epidemiology of Hodgkin's disease. *JAMA* 222:1636-1639, 1972.

20. MacMahon B, Cole P, Brown J: Etiology of human breast cancer: A review. *J Natl Cancer Inst* 50:21-42, 1973.

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[Plaintiff's Exhibit 4]

SMOKING AND SMALL CELL LUNG CANCER

Histology

Small cell lung cancer (SCLC) constitutes about 15%-20% of all lung and bronchial cancers (1). It develops predominantly in the central and intermediates sections of the bronchial system. (Squamous cell carcinoma tends to occur somewhat more peripherally.) SCLC appears on light microscopy as small, spindle-shaped or lymphocyte-like tumor cells, poor in cytoplasm and with bare nuclei. Three subtypes have been described (2):

1. Giant cell type—uniform tumor, round nucleoli and scarcely developed stroma.
2. Intermediate cell type—large, spindle—or oval shaped nucleoli; also polygonal nuclei. Cytoplasm is more developed and pseudoductal structures can be found.
3. Combined type—has small numbers of squamous cells and/or adenocarcinoma structures in addition to the predominating small cell structures.

Both SCLC and squamous cell carcinoma are Type I tumors under the Kreysberg classification system.

Association with smoking

SCLC is strongly associated with smoking. Estimates of the relative risk (odds ratio) varies from 5.0-42.5 for current smokers (3-7). These estimates are comparable with the magnitude of association of squamous cell lung cancer with smoking. The attributable risk for smoking (among smokers) is estimated at 89%-97% (3,4). Similar levels of risk have been shown for both male and female smokers. Weaker associations (RR = 1.6-3.0) have been shown for passive smokers (7-9). A convincing dose-response exists between the amount of cigarettes

smoked or years of smoking and the risk of SCLC. The risk of developing SCLC decreases with smoking cessation but the rate of decrease is less pronounced compared to squamous cell lung cancer. The relative and the absolute risk of developing SCLC plateaus 20-39 years after start of smoking (3). However, the risk of SCLC is increased among smokers as early as 5-9 years after start of smoking.

Prognosis

The prognosis for SCLC is probably slightly worse than that or squamous cell carcinoma.

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PHILIP COLE, MD, DrPH
August 2, 1993

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

The deposition of WILLIAM J. WADDELL, M.D., taken pursuant to Notice and agreement for cross-examination, discovery and any other purpose allowed by law and pursuant to the Federal Rules of Civil Procedure and the Federal Rules of Evidence; all formalities waived, including the reading and signing of the deposition; before Joyce S. Oglesby, Certified Court Reporter and Notary Public in and for the State of Georgia; commencing at 10:10 a.m., Tuesday, October 19, 1993 at 4000 One Peachtree Center, 303 Peachtree Street, Atlanta, Georgia.

* * * *

[4] WILLIAM J. WADDELL, M.D.

was called as a witness herein and, having been first duly sworn, was examined and deposed as follows:

* * * *

[17] Q. No. 8 is a two-volume collection entitled Medical Records of Robert Kevin Joiner.

A. That's correct.

Q. Have you reviewed these?

A. I went through those, yes.

Q. When you say went through, tell me the level of—

A. I did—I did not read them carefully. I just skimmed through them to see if there was anything in there that might be pertinent.

Q. Was there anything pertinent?

A. Well, the diagnosis is pertinent, his smoking history and drinking, things like that.

Q. What do you understand the diagnosis to be?

A. Small cell carcinoma of the lung.

Q. And you mentioned there was a smoking history?

A. That's correct.

Q. What do you understand that to be?

A. Well, it's highly variable in there. It varies anywhere from 1 pack a day for 8 years to 2 packs a day for 15 years, so there must be something. It's hard to say exactly what it is.

* * * *

[24] Q. When did you make your opinion in this case? How long had you had the case before you reached your conclusions on it?

A. Well, once I learned that it was cancer of the lung, I had trouble believing it was caused by PCBs, and so I would guess from the very—from very early on [25] because I've sort of kept up with PCBs. My interest—My research interest is in chemical carcinogenesis, and I'm interested in what kind of chemicals do cause cancer, and I know that the literature does not show that there's any causal relationship between PCBs and lung cancer.

* * * *

[32] Q. And that methodology of using animals is, in fact, scientifically accepted in the community as a whole?

A. The method is accepted—is accepted and is appropriate and proper, but the information cannot be blindly extrapolated to humans. It must be extrapolated with great caution.

* * * *

[38] Q. Adipose tissue.

A. In my adipose tissue, I would guess that one part per million, something like that.

Q. What do you think the national averages are?

A. Well, the NHATS report is the best one. That's the most comprehensive of levels throughout the country, in which they took autopsy samples and analyzed them for a wide variety of chemicals, and I think the extrapola-

tion was in—in the late '80s that 95 percent of the people would have at least one part per million, something like that.

* * * *

[41] Q. Do you know of a number that you can say that is the safe dose [of PCBs]?

A. Well, are you trying to get at the calculations that have been made by the EPA and others as far as what they consider a safe dose in—

Q. No, sir, I'm trying to get your opinion as to what you consider a safe dose.

A. My opinion?

Q. Yes, sir.

A. Well, my opinion is that—that the doses to which people have been exposed currently are all safe, including those in—in manufacturing and industry because we don't see any health effects from those. There are no health effects that are consistent and [42] reproducible that have been demonstrated for any exposures currently. The only adverse affects were those early on in the '30s or so in which they had apparently massive exposures and yellow atrophy of the liver.

Q. How about furans, polychlorinated dibenzofurans, what would be a safe level of contamination?

A. Sir, I'd have—I'd have to answer the same way. We don't have specific information on that.

Q. You don't consider the Yusho studies to show some correlation between the adverse human health effects and furans?

A. We don't know what the dose was. There's no way to calculate the dose because the technology at the time was not good enough to say how many furans and how many chlorophenols and other things were in there, so there's no way to calculate a dose.

* * * *

[46] Q. But your opinion with respect to dioxins and furans and PCBs is all the same, that is that the levels to which people have been exposed have not caused any human health effects?

A. That's correct, the ordinary levels that people have been exposed, yes, they're all the same.

Q. And you believe there are safe levels of furans and dioxins, but you're not prepared to tell me today what they are?

A. Absolutely, there are safe levels.

Q. And what are they?

A. Well, the levels to which people are exposed today and have in their blood and fat today are safe because there's no evidence of adverse health effects from these.

* * * *

[54] Q. You tell me that you—What do you do to maintain currency in the PCB world?

A. I keep up with the literature.

* * * *

[57] Q. Okay. Why is it that you keep up with PCBs?

A. Well, it's an interesting group of chemicals [58] because they're not nongenotoxic, and there's a widespread interest in them. I keep up with those and other nongenotoxic chemicals such as phenobarbital, and the—the analogies between those. You know, there are certain chemicals that offer us some clues about the mechanism of carcinogenesis.

And phenobarbital, of course, is another interest of mine from medical school days for the reasons I've just. . . You know, this—this clinical treatment of phenobarbital poisoning that I developed is still in clinical use today, so, you know, I've kept up with it, kept an interest in phenobarbital. And since it is not carcinogenic and is in widespread use and yet it is carcinogenic to animals, it makes a very good surrogate for looking at the differences between cancer in animals and in humans. And the same thing is true of the chlorinated hydrocarbons which cause cancer in animals but not in humans.

And so, the—the question is why do the compounds cause cancer in humans—in animals and not in humans. Something is wrong with the animal model, and so what

is wrong with the animal model? That's why I keep up with them.

* * * *

[59] Q. Well, I want the ones that in any way support your opinions in this case that Mr. Joiner does not have cancer, nor does any other human on earth have cancer because of polychlorinated biphenyls.

A. Fair enough. And I think that the answer is that the—the— There are several answers to that. The— The studies in experimental animals that show cancer from PCBs in animals are enormous doses. They're at the maximum-tolerated dose, as are the substance—many of the other substances that cause cancer in animals and not in humans. They're given at the maximum-tolerated dose.

The maximum-tolerated dose was devised as an expedient 30 years ago to try to screen for compounds that might be carcinogenic, and those were in our early days of understanding of the mechanism of carcinogenesis when we thought that there were two kinds of compounds, those that were safe and those that were—caused cancer. It was a naive understanding of cancer, which [60] today has proved wrong. In other words, we can't separate them that way. It looks more and more like it's merely the dose that causes the cancer. And so, the question is: Why does a high dose? Because more than half of all the compounds, the thousands of compounds that have been tested in the NCI Assay at the maximum-tolerated dose cause cancer in rodents, and the cancer is a liver cancer. And yet, if we look at liver cancer in humans, it's actually declining at a time when humans have been continually exposed to these same compounds.

If you plot the incidents and death rate from cancer of the liver, it's declining in the United States and steadily. It's one of the lowest ones. And the evidence is that virtually all liver cancer is due to cirrhosis. And the debate among hepatologists now is that there is not

a case, documented case of liver cancer in humans that does not have cirrhosis, either from a hepatitis virus or some other reason of cirrhosis. It's the damage from cirrhosis from either alcohol or viral infection that causes liver cancer in humans. And yet, virtually all of the cancers in experimental animals are liver cancers.

So, we have to come to the obvious conclusion that the experiments done with NCI Assay in rodents that produce liver cancer have no [61] predictability for human cancer. And the question as far as a mechanistic explanation that those of us who are interested in mechanism are toying with is what does explain that the high dose causes liver cancer in rodents.

Q. If it's your opinion that the study of cancer in animals cannot be extrapolated at all to humans, is it just animal cruelty to continue to cause animals in laboratories to get cancer?

A. At the maximum-tolerated dose, it's my opinion that it's worthless, that we now have enough database to where we need to stop doing that, that the database is adequate now of the maximum-tolerated dose in rodents, and I'm not alone in this feeling, that the further ex— further experiments on rodents at the maximum-tolerated dose will add nothing to our information.

Q. Is your feeling widely accepted in the scientific community and do you find—

A. It's accepted by very—some very prominent scientists.

Q. Is it widely accepted in the scientific community?

A. I—It depends on who's voting.

Q. In other words, this opinion, like some of [62] the other ones you've told me about is—there is indeed a split decision?

A. Well, let's put it like this, Michael: There—There are a number of senior scientists that see it the same way I do. They probably numberwise are in the minority. There are a lot of young scientists that are going with

the flow and have—do not have the perspective. So if you actually took a vote, the senior scientists that have it in perspective that think it's of no value, would be in the minority. Yet, to my way of thinking, those are the scientists whose votes count more.

* * * *

[64] Q. Lucy Anderson's done two studies.

A. She's done many more than that.

Q. That I'm interested in that we've talked about with—

A. Okay.

Q. —Dr. Robertson and Dr. Schecter. Are you familiar with those two?

A. Those two, right.

Q. About mice and lungs.

A. Fetal—Newborn mice, suckling mice.

Q. Do those studies have any validity at all in human beings?

A. No.

Q. Why not?

A. Well, because it's only in newborn mice, and the enzyme systems, the P450 systems in newborn mice are not developed yet. They don't develop until about the time of weaning. They wean at about three weeks of age, and these studies were all done before three weeks of [65] age, in which the enzyme systems are not developed yet. That's—That's one thing, so that inducing agents during that period of time probably have no relevance to inductions of those enzymes as an adult. And there is the obvious difference that these are just strains of mice, and we don't know what those sorts of—how we can extrapolate those because they're unique kinds of experiments.

Q. Speaking of infants, if you have a grandchild, would you allow them to play in a room that had air-

borne concentrations of 50 parts per million, what the EPA would consider a PCB-contaminated room?

* * * *

A. I have no problem with that as far as that causing cancer. Let's put it like this: There is no evidence that PCBs cause cancer, no matter what the age of exposure is. Otherwise, we would be seeing an increase in cancer of the lung, other than that caused by smoking, and we don't see that. The cause of lung cancer is smoking, and that's the only identified thing that we [66] have.

* * * *

[67] Q. In fact, you think that the ban on PCBs is not necessary; is that correct?

A. The ban on PCBs is probably what—was probably premature. If we can find good substitutes, there's no—there's no problem with banning anything. I think that the main problem with the PCB question is the fanatical attention we're paying to cleaning up PCB [68] contamination, which—which is totally unnecessary.

* * * *

[79] Q. And that's consistent that you do not worry about PCBs in humans at all?

[80] A. That's correct.

Q. And that would be both for people like us who wear neckties and people who work in factories where they make capacitors?

A. The levels that people are exposed to now, there's no evidence at all that they have any adverse health effects.

Q. What about those studies from Bloomington, Indiana that Greg Steele and some other people did on high levels of brain cancer among capacitor workers at that plant?

A. What about them?

Q. Is that some evidence that it may have an effect at least on that particular kind of cancer?

A. No, because the epidemiology studies have no consistency and no specificity. They vary from one study to another, and they're—none of them are significant. We have the Hill criteria which we have to use for epidemiological studies.

Q. What's the Hill criteria?

A. Strength of the association, specificity of association, consistency of the association, temporality of the association, dose response, experiment, analogy. Those are criteria that we would have to use in epidemiological studies, and the main ones are [81] consistency and strength. All of these studies are very weak associations, and there is no consistency. If it causes brain cancer in one study, malignant melanoma in another, lymphomas in another, you've got to ask the question if the strength is very low and the power is such that we can't say that it really does it, on balance, it's noise in the data, and that's what we have.

Q. Could it be that PCBs and their—And when I've been talking about PCBs, I've been including contaminants such as furans at levels that would be—

A. Of course.

Q. Have you?

A. Yes, of course.

Q. Would it be a possibility that the variation in the findings bring cancer in one cohort and a malignant melanoma in another cohort, liver disease in another cohort that concern you so that they're not all consistent, isn't there some environmental factor for each cohort that is initiating the cancer and that the PCBs just come along and promote it in some efficient fashion? Why isn't that a possibility?

A. Well, because there's no strength to those associations. All of them, even—All of them are either nonsignificant by statistical calculation or those that are significant are barely significant, meaning that [82] the 95 percent confidence of the lower level—the lower limit of

the 95 percent confidence to normal is barely over 1. We have seen enough studies in which we have epidemiological studies that still is within the noise of the data.

* * * *

[83] Q. What do you think about the individual susceptibility, a given person may have a higher potential because of their own personal genetic makeup to be affected by a chemical than other members in the group. Is that possible?

A. Anything is possible.

Q. I mean, are we all, as you said, regularly exposed to things that are cancerous at least in rats? Are we all also exposed to things that we know are cancerous in humans, like second-hand cigarette smoke, car exhaust?

A. I think the second-hand cigarette smoke is debatable, whether that causes cancer.

Q. Well, first-hand cigarette smoke?

A. First-hand cigarette smoke, there is no doubt. I don't think that there is any reasonable scientist that would deny that cigarette smoking causes lung cancer.

* * * *

[89] Q. Well, assume that this transformer may be fully repaired or it may eventually get hit by lightning and spill all over somebody's yard. Should they be warned that there's any health hazard whatsoever associated with it? Should they be told not to inhale, ingest or absorb any of that chemical? Or is the risk simply just so low that you don't think they need any warning whatsoever?

A. Well, let's just say that the risk is from the—the track record that we have on PCBs in fluids and transformers is such that no one has been injured—has had health effects from those exposures.

Q. So, therefore, based on the history that you know today and what you believe the history to be in the future or what the future holds, there would be no need to warn against inhalation, ingestion or absorption of that chemical; is that correct?

A. Based on the epidemiology we have now and the track record we have and what exposures have been, there is no evidence that there would be a situation [90] which there would be adverse health effects. Anything is toxic if the dose is high enough. You can kill yourself by drinking too much water.

* * * *

[93] Q. With respect to cancer, what's an initiator and what's a promoter?

A. Well, the current theory, hypothesis is that an initiator is something that attacks the DNA, that alkylates or in some way changes the DNA in a cell. And a promoter is something that promotes the cell's dividing once it has been initiated to make it grow more.

Q. Is cigarette smoke an initiator?

A. It is.

Q. Is it a promoter?

A. Probably.

* * * *

[97] Q. Do you think that the concept of initiation and promotion has anything at all to do with Mr. Joiner's onset of lung cancer?

A. I would have to say we don't know. We—We don't know, but I think that we can answer as far as the specific case of Mr. Joiner that promotion—that we have no information that would lead us to believe that the PCBs promoted the initiation from the—from the cigarette smoke and had any significant effect on his development of lung cancer.

Q. Do you think that PCBs can promote any cancer?

A. No. There no evi—information that they can promote any cancer in humans.

[98] Q. Do you think there's information that they have promoted cancer in animals?

A. Under specific circumstances, like the Lucy Anderson papers. There are some circumstances in which they

have been interpreted to be promoters in experimental animals.

Q. Do you think that they can initiate cancer in animals?

A. There's no evidence that they can initiate cancer. They're called nongenotoxic.

Q. With respect—Can furans initiate cancer?

A. No.

Q. Dioxins?

A. No.

Q. All of those three are promoters?

A. All those in experimental animals can be promoters. They can also be inhibitors.

Q. Are furans promoters in humans?

A. In humans?

Q. Yes.

A. There's no evidence that they are.

Q. Are dioxins promoters in humans?

A. No evidence that they are.

* * * *

[99] Q. [. . .] [100] Describe for me the science of toxicology.

A. The science of toxicology is the study of the adverse effects of chemicals.

Q. Describe the scientific evidence that a toxicologist considers when—And I want these answers to be relevant to the PCB case and your analysis and opinions in this case involving Mr. Joiner, please.

What kind of evidence would you consider as a toxicologist?

A. What kind of evidence I would consider? I would consider primarily epidemiological evidence.

Q. Epidemiological evidence concerning populations of human beings?

A. Populations of human beings. That's the definition of epidemiology.

Q. What role does human epidemiological studies play —do human epidemiological studies play in the determination of the toxicity of any substances?

A. Epidemiology plays a—a prominent role because that's the final species to—in which we're interested. Experimental animals cannot predict; they only give us some clues and the suggestion of ways to go in humans, but ultimately, the epidemiological studies [101] are those on which we must rely.

Q. What do you understand to be the state-of-the-art causes of human cancer or have we already discussed that moments ago?

A. State-of-the-art causes of human cancer? That's pretty broad. What do you want me to talk about?

Q. Well, Mr. Freeman wrote me the question. I'm just trying to see if I understand it.

It says here that you "would be able to testify as to the state of the art as to what is known regarding the causes of cancer in humans, generally." What is your opinion on that?

A. Well, there are a few known causes of cancer in humans. One is cigarette smoking. Another one is hepatitis virus. There are a few known causes of cancer in human.

Q. Do you believe that cancer in humans is growing at a—as the percentage of the population is at the rate it's growing?

A. The incidents [*sic*—incidence] and death rate from cancer is increasing currently only because of the incease in lung cancer. If one takes the lung cancer out of the cancer statistics, then there is an overall decine in cancer in the United States.

* * * *

[109] Q. What do you understand that Mr. Joiner suffers from?

A. Small cell carcinoma of the lung.

Q. What do you believe caused it?

A. Smoking tobacco.

Q. And what was his statistical chance of being diagnosed with small cell carcinoma at the age of onset?

A. I don't have a number, but it's low because he developed it at a relatively low age, and the number of people that develop cancer of the lung from smoking decreases with decreasing age.

Q. Well, you saw in Dr. Robertson's testimony that he had introduced or had with him a study that had some statistics. Do you think that they would be off base?

A. The stat—Would the statistics be off base or the interpretation be off base?

Q. The statistics.

[110] A. I don't know specifically what the statistics were, but they probably were the sera data from the National Cancer Institute. That's what everybody's using, and they probably show a very low incidence at—at 20 years of age, 30 years of age with increasing at each 5-year interval. So what? We know that there are people that have—that develop cancer in their 20's from smoking for a few years. Some people are simply more susceptible than others. We do not know the reason. The only thing we can infer is that there is a genetic predisposition in some people.

* * * *

[111] Q. Well, the way that Lucy Anderson did it, it appeared to be a promoter there; is that correct?

A. Well, but that was in—that was in suckling mice whose enzymes are totally different, totally different. We published papers on this many years ago about how the enzymes do not mature in mice until the—essentially the time of weaning, which is about three years—three months —three weeks of age. And so, if you take suckling mice, you can get all sorts of curious effects.

Q. At least in that particular example, it did appear to be a promoter; is that correct?

A. In that particular situation, but Mr. Joiner is not a suckling mouse.

* * * *

[112] Q. Have you ever heard of the World Health Organization?

A. Yes, sir.

Q. Are you familiar with their recent thing that Dr. Teitelbaum discussed, their publication called the International Program on Chemical Safety?

A. I'm familiar with the IPCS.

Q. Okay. Are you familiar with the one on Polychlorinated B[i]phenyls and Terphenyls, Second Edition?

A. I can't recall.

Q. Well, it's just come out in the last month or two, if you've seen it. It's a red book.

A. I don't recall seeing it, no.

Q. On page 478 of that publication, it says, "Taking the combined evidence from human and experimental animal studies, the IARC group concluded that PCBs are probably carcinogenic for humans." Then it has a parenthesis, IARC, 1987, closed parenthesis, period.

What is your reaction to that phrase?

[113] A. That phrase is just another way of saying that it's been found to be carcinogenic in animals. That's all that—I've been to the IARC discussion, I've been there a couple times and participated in those workshops, and that's all that means. If it's found to be carcinogenic in animals, then it's presumed to be carcinogenic in humans, but there is no evidence that it's carcinogenic in humans, and that document will so state.

Q. So, the word "probably" carcinogenic for humans doesn't mean that at all?

A. That does not in the sense that you're talking about.

* * * *

[116] Q. Did you read Dr. Schecter's deposition?

A. I read the excerpts prepared by Teitelbaum's staff.

Q. What did you think of his thoughts?

A. Well, I—I completely disagreed with his interpretation of what happens when you lose body fat. I think he's just going in exactly the wrong direction, and I think all the scientific information will back me up on that.

Q. What about his other opinions, that PCBs are not good for humans and nor are furans or dioxins?

A. I think he's exaggerating the information we have available.

Q. Mr. Freeman handed me this morning the [117] following with respect to the opinions that he expects you to provide at the trial: Number one, "That there is no scientific evidence that PCBs are an initiator, co-carcinogen or promoter of, one, small cell carcinoma of the lung in humans or, two, any malignancy in the human lungs," Is that your opinion?

A. That's correct.

Q. And we've talked about how you arrived at that opinion already, haven't we?

A. I think we have.

Q. Number two, "There is no scientific basis upon which to conclude that Mr. Joiner's small cell carcinoma of the lung was caused by his exposure to PCBs"?

A. That's correct.

Q. And it would be, regardless of the dose, you just don't think that there's any way you can get lung cancer from PCBs; is that correct?

A. That's correct.

Q. So, we're not arguing about the level of exposure because there is no level that you believe could cause lung cancer; is that correct?

A. There is no information in humans that PCBs cause cancer of the lung at whatever dose. There is—

Q. What about furans?

[118] A. No information.

Q. Dioxins?

A. No—No evidence that they do.

Q. Number three, "The only recognized cause of small cell cancer of the lung is exposure to cigarette smoke."

A. That's correct.

Q. And you've talked to me about that already; is that correct?

A. Right, I think so.

Q. Is it your further opinion that a small cell cancer caused by cigarette smoke could not be promoted by any other chemical?

A. In humans, I think there is no information that it would be promoted by anything.

* * * *

[119] Q. Number four, "Mr. Joiner has not received a toxicologically-significant dose of PCBs. His adipose tissue level is well within established ranges for concentrations reported in the general population."

That's part of your opinion?

A. It is.

Q. And we've talked about that a little bit?

A. I think we have.

Q. What is a toxicologically-significant dose of PCBs?

A. Well, it's a dose—I can't tell you what it would be, but it certainly would be above that.

* * * *

[123] Q. The second portion of this number four was, "His adipose tissue level is well within established ranges for concentrations reported in the general population."

You told me earlier that you would expect that to be around one part per million?

A. Yes, and because I think the NHATS thing said that 95 percent of the population, and I think that was in 1988 or '89. I can't remember. The NHATS thing was discontinued about '84 or '85, but they had enough information to make projections about what the levels were and how they were increasing in numbers of people. I—I've got a slide on that, but I—

Q. Are you familiar with the work done on these PCB levels that was published in "Chemisphere" by some scientists at the CDC; they did about 5,000 samples?

A. I probably have seen that.

* * * *

[124] Q. This last thing that we talked about, number five, "There's no scientific basis to believe that weight loss diminishes concentration of PCBs in the adipose tissue." We've talked about that, have we not?

A. Yes.

* * * *

[Plaintiffs Exhibit 1]

WILLIAM JOSEPH WADDELL

Date and Place of Birth:

March 16, 1929, Commerce, Georgia, USA

Marital Status: Married, 3 Children

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Education:

A.B., (Chemistry), University of North Carolina, 1951
M.D., University of North Carolina, 1955

Fellowships:

Public Health Service Postdoctoral Research Fellow, Department of Pharmacology, University of North Carolina, 1954-1958
National Institutes of Health Special Fellow, Department of Pharmacology, Royal Veterinary College, Stockholm, Sweden, 1965-1966
Scholar, Sloan Foundation, Health Sciences Consortium, 1974-1975

Academic Appointments:

Assistant Professor of Pharmacology, School of Medicine, University of North Carolina, 1958-1962
Associate Professor of Pharmacology, School of Medicine, University of North Carolina, 1962-1972
Associate Professor of Oral Biology, Dental Research Center, University of North Carolina, 1967-1969
Professor of Oral Biology, Dental Research Center, University of North Carolina, 1969-1972
Professor of Pharmacology, College of Medicine, University of Kentucky, 1972-1976
Professor of Oral Biology, College of Dentistry, University of Kentucky, 1972-1976
Adjunct Professor of Pharmacology, School of Medicine, University of Louisville, 1972-1976
Adjunct Professor of Pharmacology, College of Medicine, University of Kentucky, 1977-
Professor of Pharmacology and Toxicology, School of Medicine, University of Louisville, 1977-
Visiting Professor of Pharmacology and Toxicology, Schools of Medicine and Pharmaceutical Sciences, Showa University, Tokyo, Japan, November 1983-May 1984

Honors:

Centennial Alumnus Distinguished Visiting Professor, School of Medicine, University of North Carolina, February, 1979

Administrative Appointments:

Associate Division Director, Center for Research in Pharmacology and Toxicology, University of North Carolina, 1966-1967
Associate Director, Dental Research Center, University of North Carolina, 1968-1972
Director of Graduate Studies in Pharmacology, University of Kentucky, 1974-1976

Chairman, Department of Pharmacology and Toxicology, University of Louisville, 1977-

Society Memberships:

American Physiological Society, 1973-
American Society for Pharmacology and Experimental Therapeutics, 1958-
American Teratology Society, 1968-
Association for Medical School Pharmacology, 1977- (Secretary 1986-1988; President 1988-1990)
Sigma Xi, 1958-
Society for Experimental Biology and Medicine, 1956-
Society of Toxicology, 1978-
Ohio Valley Chapter of Society of Toxicology, 1983- (President 1983-84)
Royal Microscopical Society, 1986-
International Society for the Study of Xenobiotics, 1989-
Fellow, Academy of Toxicological Sciences, 1992-

Consultant:

Research Triangle Institute, 1965-1972
Block Drug Company, 1968-1972
Becton, Dickinson and Company, 1971-1972
Baxter-Travenol Laboratories, 1974-1980
Faculty of Medicine, University of Kuwait, 1977-
Baby Products Company, Johnson and Johnson, 1977-1982
Procter and Gamble, 1978-
Allied Chemical, 1978-1982
American Cyanamid, 1981-1987
Dow Chemical, 1981-1986
R.J. Reynolds Industries, Inc., Scientific Advisory Board, 1985-1988 (Chairman 1987-1988)
CA Blockers, Inc., 1987-1989
Grain Processing Corporation, Inc., 1988-
Norwich Eaton Pharmaceuticals, Inc., 1988-
Distilled Spirits Council of the United States, Inc., 1989-

Board of Directors:

Computer Assisted Teaching Systems (CATS) Consortium, 1977-1983
Pharmacon Research Foundation, Inc. (Chairman), 1979-

Editorial Board:

Drug Metabolism and Disposition, 1972-
Toxicology and Applied Pharmacology, 1981-1989

University of Kentucky Committees:

College of Medicine Second Year Curriculum (Chairman), 1973-1975
College of Medicine Second Year Promotions, 1973-1975
College of Medicine Educational Policy, 1972-1976
College of Medicine Pharmacy and Therapeutics, 1972-1976
Student Evaluation and Academic Policy for Second Year (Chairman), 1975-1976
Academic Area Advisory Committee for Biological Sciences, 1974-1976 (Chairman, 1975-1976)
Graduate School Fellowships for Biological Sciences, 1974-1976 (Chairman, 1975-1976)
Ad Hoc Committee to Review College of Pharmacy (Chairman), 1976
Ad Hoc Committee to Review Institute of Environmental Sciences, 1976

University of Louisville Committees:

School of Medicine Biomedical Hazards Committee (Chairman), 1977-1983
School of Medicine Insitutional Self-Study Task Force for LCME Accreditation (Chairman), 1979-1980
School of Medicine Radiation Safety Committee (Chairman), 1980-1983

Cancer Center Advisory Committee, 1978-1983
Biological Hazards Committee, 1980-1983

Commonwealth of Kentucky Committees:

Kentucky Drug Formulary, 1977-1981
Kentucky Tobacco and Health Institute Technical Advisory Committee, 1977-1983
Kentucky Medical Assistance Program, 1978-1981
Kentucky Heart Association Research Review Committee, 1980-1981

National Committees:

Guidelines for Detection of Hepatotoxicity Due to Drugs and Chemicals; Fogarty International Center, 1978
Reproductive Effects Assessment Group (Teratology); Environmental Protection Agency, 1980
Educational Affairs Subcommittee of ASPET: New Approaches to Teaching Pharmacology, 1980-1983
ASPET/SOT 1982 Joint meeting in Louisville, Local Committee Chairman
Educational Affairs Committee of ASPET, Chairman, 1983-1986
Society of Toxicology Committee on Information Handling, 1986-1988
FASEB Education Committee, 1986-1989
Texas Coordinating Board, review of teaching programs, 1983, 1985, 1987, 1990

International Committees:

Alfred Benzon Symposium III, Copenhagen and Lund, Ion Homeostasis of the Brain, May, 1970
International Agency for Research on Cancer, Alcohol Drinking, Lyon, France, October, 1987
International Life Sciences Institute, Ethyl Carbamate, Brussels, Belgium, June, 1989

WILLIAM J. WADDELL

Publications

Butler, T.C. and Waddell, W.J.: A pharmacological comparison of the optical isomers of 5-ethyl-5-phenyl hydantoin (Nirvanol) and of 3-methyl-5-ethyl-5-phenyl hydantoin (Mesantoin). *J. Pharmacol. Expt. Ther.* 110:120-125, Jan. 1954.

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Waddell, W.J.: A simple ultraviolet spectrophotometric method for the determination of protein. *J. Lab. Clin. Med.* 48:311-314, Aug. 1956.

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Waddell, W.J. and Butler, T.C.: The distribution and excretion of phenobarbital. *J. Clin. Invest.* 36:1217-1226, Aug. 1957.

Butler, T.C. and Waddell, W.J.: Metabolic deethylation of 5,5-dimethyl-3-ethyl-2,4-oxazolidinedione (Dimedion). *Arch. Int. Pharmacodyn. Ther.* 111:308-313, Aug. 1957.

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

The deposition of DR. WILLIAM CHARLES BAILEY, taken pursuant to Notice and agreement of counsel and pursuant to the Federal Rules of Civil Procedure and the Federal Rules of Evidence; all formalities waived, excluding the reading and signing of the deposition; before Robin B. Myers, Certified Court Reporter and Notary Public in and for the State of Georgia; commencing at 9:05 a.m., Friday, October 29, 1993 at 1600 The Candler Building, 127 Peachtree Street, Atlanta, Georgia.

* * * *

[4] DR. WILLIAM CHARLES BAILEY
was called as a witness herein and, having been first duly sworn, was examined and deposed as follows:

* * * *

[22] Q. Do you think PCBs could have any effect on the respiratory system if you inhaled it?

A. I know of no documentation or literature that there is, you know, a human cause of this in the human literature.

* * * *

[23] Q. When you say it would not be an unsual thing, is that because physicians often look at animal research to see whether or not there could be a correlation between a given set of circumstances with [24] animals and that same set of circumstances with humans?

A. Well, it's really a little different from that. What is done often is—is animal studies allow one to know

specifically whether or not you want to look in humans for specific things, but then you really can't necessarily correlate animal research to human research until the human research has been done. But clearly, if there would be—it's fairly common in drug studies, for instance, that drugs are used in animals first and if there are any kind of problems in animals, those specific things would be looked at, but—you know, in humans to make sure there wasn't a problem. Most of the time most of the animal research is done at very high doses of things to sort of overwhelm the animal in a sense, and if there's any possible chance of causing disease, then—then it may be seen, and then you begin to try to correlate that to what the human dose might be and see—and look specifically in those areas. But before you can really draw any conclusions about humans, you have to have data on humans, obviously, because they're different.

* * * *

[26] Q. Are you aware of any human health effects associated with dioxin exposure?

[27] A. I'm not aware that dioxin exposure can cause lung cancer or specifically small cell cancer, which was the particular human effect I was interested in in reviewing that literature.

* * * *

[28] Q. Are you familiar with the United States Government's position on dioxins and the association of dioxins in human injury?

A. I'm familiar with a recent report that was produced.

Q. What is your understanding of that report's conclusions concerning lung cancer?

A. I—I actually am confident of what that conclusion is because I just looked at that, and they found really no real evidence of lung cancer and specifically no real evidence of small cell cancer in that exposure.

Q. Which report are you referring to? Do you know the publication that that—

A. The two- —The two-volume set on—that was just published. The chairman of that report was—well, you know, it was just—just published recently, but I—

Q. Within the 90 days?

A. Yeah.

* * * *

[30] Q. Are you aware of any dangers to human health associated with polychlorinated biphenyls?

A. Well, yes.

Q. What are those?

A. It seems to me the—the human data—dangers have been documented. They're primarily some skin problems, chloracne and liver dysfunction.

Q. Any other functions—problems whatsoever?

A. Well, those are the only things that I am familiar that were, you know, have been documented beyond a shadow of a doubt.

Q. Are there any that have been documented not beyond a shadow of a doubt but nevertheless there are some studies supporting claims?

A. Well, of course, I—I basically looked at the literature to draw two conclusions. What were the things that clearly beyond a shadow of a doubt could be caused by PCB, and I think I shared that with you. And then I looked specifically, is there really even any circumstantial evidence that small cell cancer, which is what this man has, could be caused by PCB and found no [31] evidence, even circumstantial or partial or, you know, inconclusive that that might be considered. So, that was kind of, you know, once I went through the literature and came to those conclusions, I really didn't feel like I needed to examine some of the other, less pertinent bits of information.

Q. Well, did you find any information that in any way would have led you to believe that PCBs are a probable human carcinogen?

A. Well, the only data that I saw that's—that's pretty definitive is that it can cause carcinogen in animals, and

so, therefore, you need to be aware, and that's why human studies need to be done, to make sure. But again, I looked specifically for lung cancer and specifically small cell cancer, and no evidence whatsoever that they're—

A. Well, yeah. I—I really don't know the details of—

Q. Well, would you classify it from all the documents that you have read as a probably human carcinogen?

A. Well, I didn't really examine it from that standpoint. I examined it from the standpoint of: Is it likely or even possible that it could have caused small cell cancer, and it's so clear that small cell cancer is caused by cigarette smoking, and there was not even any circumstantial evidence in the literature that it might [32] be related to PCB that I didn't really need to pursue that issue any further.

* * * *

[39] Q. We've just talked about some known dangers of PCBs, and you told me about the skin problems and the liver problems. How about dibenzofurans? Are you aware of any known dangers associated with those chemicals?

A. Well, yeah. I—I really don't know the details of—of these other chemicals and didn't really pursue those in as much, you know, thoroughness, other than looking specifically for the possibility of small cell cancer. And so, the only thing I can say with any confidence to you because it's the only thing I really looked at specifically was that those agents have never been associated with the development of small cell cancer in humans.

Q. How about dioxins?

A. The same thing.

* * * *

[44] Q. [. . .] Why do you think that the table in Plaintiff's Exhibit No. 2 is relevant to your testimony today?

A. Well, one of the things that—that I was looking at is the overwhelming evidence that small cell cancer is exclusively caused by cigarette smoking. And—And so, what we'll do is when we get to the particular table that relates to that is we'll see that, you know, about 99-plus

percent are associated with— [45] you know, documented to be associated with cigarette smoking, and the random misclassification could certain account for that one percent or less.

Q. Okay. What's this next one, No. 3?

A. Let's see. . . This particular table deals with—This particular table deals with various diseases and—from, you know, coronary heart disease, COPD, cancer of the lips, lungs and so forth in both males and females and the attributable risks, taking all cancers or all specific things. This doesn't particularly take out small cell cancer, where one would say almost a hundred percent of small cell cancer would be attributable to—to cigarette smoking. But these would include, for instance, asbestos workers and a number of other people. And the point here is that 90 percent of men, the attributable risk for lung cancer, you know, can be related specifically to cigarette smoking.

* * * *

[48] Q. Plaintiff's Exhibit No. 4.

A. Uh-huh (affirmative), right, okay. This one relates various cell types. As you know, lung cancer can be, you know, a number of different cell types, epidermoid, small cell, adenocarcinoma, large cell and bronchioloalveolar cell carcinoma, five different cell types, and the question here is, you know, what—which of these cell types are related to smoking or more related to smoking and so forth. And you can see here the total numbers, and then you have it in males and females, and so they're—small cell cancer, you have 640 total. This is from the Mayo Clinic, and so these [49] are 640 cases that have gone through the Mayo Clinic. And 533 of those were men that were smokers, and only 4 of the 533 were nonsmokers. And then in women, it's 103.

So, basically, when you—you're talking about really almost—really more than 99 percent of these people were actually smokers and who developed small cell cancer.

Q. Does that chart tell you when the onset of the small cell cancer was, at what age?

A. It doesn't tell when the onset was, it doesn't deal with whether or not they quit smoking or not. It just says that they had been smokers; that's all it says.

Q. Okay.

A. And so, basically, it pretty well documents, and if you think about this first chart that we went over about the possibility of random misclassification, you—these 533 smokers would not have been randomly misclassified, you know, but 4 of the nonsmokers could've been. So, it's conceivable that they were. It's also conceivable, as you say, that—that they may have been—had passive smoking, you know, environmental smoke, as well.

Q. With respect to No. 4 here, that you just had in your hand, —

[50] A. Uh-huh (affirmative).

Q. —does that chart or study show in any fashion whether or not any of the small cell cancer victims had been subjected to any known cancer promoters in addition to their cigarettes?

A. Well, this chart deals strictly with cigarettes, which is basically what we've already seen from the other attributable risk chart; that is, 90 percent of the attributable risks for all cancers, and in this case, it looks like it's 99 to 100 percent of the attributable risk for small cell cancer.

* * * *

Q. Okay. No. 5 here.

A. Okay. No. 5 was basically a printout of one of the questions that—that I was asked was how unusual is it for somebody to be in their 30s when they develop lung cancer, and I said that's relatively unusual, but not unheard of. I mean, I've seen some in their 20s. Personally I've taken care of patients who have developed lung cancer, and so basically, you know, after I was [51] asked that question, I just called our cancer center and asked the statistical people did they have a good printout of all the cancer patients we have. They said, no, they really

didn't, but they could get a few things, like people who had had surgery in the last several years or something like that. And so, this is people that were on the surgical list on the computer in the last five years from the cancer center at UAB. So, these would just be Birmingham patients, under 40.

And actually there is 27 names, but 1 of them, for some reason it looks like it's the same name, Annie B. and Annie Raspberry (ph), so I think it's really just 26 people here over a 5-year period. And as you can see, there's some—some of these cancer patients are 29 and 28, plenty of 30s. And so, like I say, it's—it's unusual, but by no means unheard of, and I see patients like that all the time that do develop cancer.

Q. How many total patients did UAB see for lung cancer?

A. You mean what percentage would this represent?

Q. Yes, sir.

A. I would—I would guess this would represent a relatively small percentage, 10 percent or so, say, of the lung cancers, but I really don't [52] know specifically?

Q. You don't know?

A. No, unh-unh (negative). I would say in my own personal experience that, you know, I personally have seen several people in their 20s that have developed lung cancer, and I've probably seen hundreds of people with lung cancer, and so as far as people in their 20s, I would say that's very rare, you know, what may be less than one percent, just of my own personal experience.

But in the 30s, you know, not all that uncommon.

* * * *

[55] Q. Now, what is No. 6?

A. No. 6, well, that was—This is again an article sort of summarizing all the studies relating to smoking in spouses, of which is among the better—you know, groups of studies with large numbers looking at the possibility of developing lung cancer in nonsmokers. One of the

questions is: Can nonsmokers develop lung cancer, and obviously, a very small percentage do. So, you know, like I say, the 90 percent of attributable risk is to cigarette smoking. And the question is: Within that 10 percent, not just talking about small cell, but all other cancers as well, is there other opportunities to be exposed to cigarette smoke. And clearly, there is if you live in the household with a husband or wife who smoke or you, as you say, go to work and are exposed to somebody or actually grow up in a home as a child. And some of the greater risks really are if the mother smokes for children and if the father smokes and so forth.

But this strictly relates to husbands and wives. And as you can see, the risks, the relative risks in all of these studies range from about two at the lowest to up to nine and—and about seven and—and two are the highest. But most of them are in the two-to-four range, meaning that a nonsmoker in a nonsmoking home has a risk of—of one, say, and that would be the [56] baseline, and if you are a nonsmoker in a smoking home, you have an increased risk of—of developing lung cancer.

Q. And the number there appears on most of the studies to hover around two; is that correct?

A. Yeah, right, two or three. That would be the average, although it goes up to as high as nine in one individual study.

Q. Is two or three—

A. Two or three times the risk.

Q. Two or three times. Can that be statistically significant?

A. Oh, sure, with large enough numbers. And this—this really is a chart that eliminates those studies that don't have large numbers to be statistically significant. So, these are—are studies that are statistically significant. There's probably about 27 or 28 studies from which these—you know that were sufficiently—

Q. What publication is this?

A. This is one of the surgeon general's reports, and this is the front page from that. It's a pretty definitive document.

Q. What is No. —

A. In fact—In fact, all of these— [57] Because I wanted to be sure there was just absolutely reputable sources, all of these come from various surgeon general's reports, and so, there's just not much question about the authenticity of the data.

Q. What's No. 7?

A. One of the other questions that was raised, not only about somebody being relatively young, was that unheard of, the question is: If you were an ex-smoker, did you still have a risk of developing lung cancer, and if you did, what was the risk and when did it fall off and so forth? And so, this is a chart that is develops—develops a model of the relative risk, one being a hundred percent, you know, right after you quit smoking, you know, if you are a smoker. And what happens, —In other words, we all know and we encourage people to quit smoking because there's so many things caused by cigarette smoking that we want to reduce, and this is specifically related to lung cancer. And of course, obviously, it depends—it can depend on whether or not—Smoking duration can make a difference. That can be a variable. It can make a difference in terms of whether it was 10, 20, 30, 40 or 50 years before or not, so this is looking at it both whether you did adjust for smoking duration or whether you did not adjust for smoking duration because that—you know, that would be [58] a variable that could be pertinent.

And as you can see, as I understand it, this particular patient got a varia—varies all over and map in terms of my review of the medical history, but from five to ten years when he quit smoking, I think the average—the average estimate is eight years that he quit smoking, but, you know, it varies from the time he developed lung can-

cer. And anything less than ten years, these two don't diverge much. And as you can see, it gets down to about seventy—above—it's a little above eighty percent, even, in this one at ten years, I think. So, the risk is reducing. And if you don't account for duration, it'll—it'll continue to reduce. But it kind of falls off at about ten years and doesn't reduce a whole lot more if you adjust for duration time.

Q. But in any interpretation, whether you adjust for smoking history or not, any person who stops smoking, —

A. The risk reduces, as you can see.

Q. —at seven years, they've—they've reached a substantial reduced risk in their reduction?

A. It's about—Well, what it is is—If you'll—You'll see this is a hundred percent; that's ninety percent (indicating) of risk, so they've gotten the risk at five years down to about 95 percent.

[59] MR. FLINT: How much?

BY THE WITNESS: (Resuming)

A. Ninety-five percent. So, it's still ninety-five percent of what it was before at five years. So, basically, five years. . . . In fact, I was surprised that it dropped that much the first five years. Most of the time, we don't start counting until after five years, you know. But anyhow, it is at ninety-five percent. It's—It's reduced by five percent at the end of five years.

Q. Okay. So, it's not—

A. In other words, that's not a very substantial reduction in risk.

Q. What is the rate for—

A. It is a statistically significant reduction, however.

Q. Okay. What—

A. It is well worthy of—well worth getting somebody to quit smoking. I mean, you know, no question about that.

* * * *

[61] Q. Would you classify lung cancer as primarily a disease of the older people?

A. Unfortunately, not anymore. It's a disease that we see—As you see, there are, you know, eight thousand—or, you know, four or five thousand deaths a year from people in their 30s or younger. And so. . .

[62] You know, when I first started in this business, basically there were about thirty thousand total cases of lung cancer per year deaths, twenty years ago or something like that, and there are a hundred and fifty thousand deaths per year now, a tremendous increase because of the number of years people have—you know, have been smoking and so forth. And so, it's a—there are—there are a large number of young people who die every year from lung cancer.

Q. When you consider the increase in smoking or increase in lung cancer rates, do you take into account, that in addition to smoking, people's lungs are also assaulted by industrial chemicals on an ever-increasing basis over the same period of time?

* * * *

A. I—You know, I don't know of anything, other than those substances that I mentioned that are associated with that, and those are a pretty specific things. I think asbestos is the main thing that's been found to be a culprit that was in any large number. But [63] we've already looked at it and can see that most of the—all the data would indicate that cigarette smoking is the cause of lung—of small cell cancer, and cigarette smoking is attributable to—is the—is the risk attributable to 90 percent of all cancers of the lung.

* * * *

Q. Well, first, what would you classify it as, primarily an initiator or primarily a promoter or would you say it's a combination of the two or some other answer?

[64] A. Well, the only thing that I know for sure because I don't know that we really understand the mecha-

nism as clearly as would be nice, is that cigarette smoking is the cause of lung cancer in—in basically 90 percent of all cases and in about a hundred percent of small cell cancer. And I don't really know that I can separate it out beyond that. In other words, I think there's a clear etiological relationship. I think that's been documented in the literature, you know, for many, many years, many, many studies, and I think when you get into this—into specifics beyond that I don't that I can really comment intelligently.

* * * *

[68] Q. Do you have an opinion on whether or not PCBs or furans, polychlorinated dibenzofurans, that is, or dioxins are promoters of any cancers in human beings?

A. You know, I don't think that there's any evidence that they're promoters of any cancers, but I know that there's no evidence of lung cancer and of small cell cancer.

Q. Do you know whether or not they've been shown to be promoters of cancer in laboratory animals?

A. I believe there's been an association with the development of cancer in laboratory animals, but the specifics in terms of the mechanism I don't know and have not pursued that. I—I know more that there is an association, and that's—beyond that, I can't give you the specific and technical details of how that association is—or at least what the theories, and I imagine it's really at the theoretical rather than the factual level of that, whether it's a promoter or how it works.

* * * *

[70] Q. Was there anything in Mr. Joiner's history, other than his cigarette smoking which you found in any way significant?

A. As it related to the development of small cell cancer, no, I did not find anything.

* * * *

[74] Q. It's my understanding from the Interrogatory [75] Responses that were provided to us that you were

going to provide us opinions on three things, and I wanted to tell you what those were and see if we've already just talked about them or if we need to go into them more.

The first one is that Mr. Joiner has not suffered any adverse health affects from his alleged exposure to PCBs. And what is your opinion on that?

A. I don't think he has. I don't think the PCB had anything to do with the development of small cell cancer, which is his—his bad health effect.

Q. Can you eliminate as a possibility the idea that Mr. Joiner initiated small cell cancer through his smoking history, but that this small cell cancer was promoted and made to come on at an earlier age because of his exposure to PCBs?

A. There's just no evidence to that effect whatsoever in the literature, and I think his small cell cancer was caused by cigarette smoking.

Q. And it is your opinion, that it could not have been promoted by PCBs?

A. It's my opinion that it was caused by cigarette smoking, and I don't know of any reason to believe that anything else had anything to do with it.

Q. If someone has initiated small cell cancer through cigarette smoking, are you aware of any chemical [76] or product or thing that they could do to promote or increase or speed up the onset of the disease? . . . I want to start with small cell.

A. Well, most of—most of the cancers that are caused by asbestos are adenocarcinoma, the synergistic thing there, but I—I really not rule out the possibility of small cell; I just don't know that for sure with asbestos.

Q. So, it's possible that some chemicals could do it or some products?

A. It—It's conceivable, but basically, if you really look at the statistic on small cell, I have in my personal opinion never seen any case of small cell cancer in anybody but smokers, people who have had cigarette exposure.

And, you know, I have—have seen a number of adenocarcinomas, which is the one that's most often associated with asbestos in nonsmokers, and that's, as you can see in that list, that's the most common thing [77] that you see in nonsmokers. And so, but I just can't speak with any authority because I don't know for sure that that has not been reported. It may have been reported, but, you know, as far as small cell cancer is concerned with asbestos. But that would be the only possibility I can think of.

* * * *

Q. The third thing we were told is that Mr. Joiner's medical complaints are attributable to causes other than exposure to PCBs or products containing PCBs, and from what you've told me today, am I correct in [78] understanding that you contributed—you attribute his lung cancer entirely to his cigarette smoking history?

A. Yes.

Q. And you absolutely do not attribute either the likelihood of the onset of the cancer or the time, that is age, at which the onset occurred to having any kind—to PCBs having been a contributing factor?

A. That's right.

Q. Do you have any other opinions in this case that you've been asked to render?

* * * *

A. Well, I mean, you didn't ask me about that, but I mean, you know, when you're just—when—when you consider the fact that his mother had lung cancer, we talked about genetic predisposition, and I think that is [79] a much more significant factor than anything else if you want to come up with another relationship to the possibility of cause.

Q. At what age did his mother develop cancer?

A. I really don't know.

Q. Do you know what age any other relative that he had developed cancer?

A. No, and again, we're—you know, I mainly responded to your questions I think in the general field of things. That's about all I want to talk about. But if you want to get down to specifics about a little bit more information regarding his risk of lung cancer and his risk of developing small cell cancer, I think—I think we have good data that his family was predisposed to the development of cancer, specifically his mother developing lung cancer and some other uncles and so forth with that problem, as well. He also had two parents that smoked. Both his father and his mother smoked, so he grew up in a home exposed to passive smoking. That's—That's really often associated with the early development of lung cancer. What happens, obviously, is you begin to get the passive smoking risk as an infant, perhaps, and that's continued for many, many years. And what happens is usually people who grow up in that sort of environment begin to smoke earlier because it's just one of those [80] things. It's just a standard—It's part of their environment, and they figure smoking is normal, so they usually begin as early teenagers or, you know, some time in that period of time.

Q. Do you know when Mr. Joiner began?

A. I think he said he was 18, but I mean, I—you know, those are difficult estimates sometimes to know for sure, but it's not unusual for—he was clearly exposed to passive smoking very early, and, you know, the statistical probability would be somebody like that would start sort of early, you know. And so, I think those factors are, you know, additionally important factors in terms of the age at which you develop lung cancer.

* * * *

[81] Q. Do you think there's any need for more studies?

A. Oh, there's always need for more studies to—to document things further, but at this point, I think there's no evidence of any health risk as far as small cell cancer is concerned, you know, in this—this particular exposure.

* * * *

[84] Q. Anything else about his health that you need to know in order to be confident with your opinion or are you as confident as you need to be?

A. Well, related to the questions at hand, yes. The question at hand is, you know, what's the cause of the small cell cancer. I think I've got the data to support that.

* * * *

[Plaintiffs Exhibit 1]

CURRICULUM VITAE

William Charles Bailey, M.D.

Date and Place of Birth:

August 4, 1939
Jacksonville, Florida

Social Security Number:

263-54-0797

Marital status:

Married June 8, 1963;
Wife: Bonnie Shaw Bailey
Children: William C. Bailey, Jr. born January 4, 1965; John Faison-Oates Bailey born April 16, 1969; Evans Cecil Bailey born October 26, 1970

Education:

Washington and Lee University, Lexington, Virginia, 1961, B.A. Tulane University School of Medicine, New Orleans, Louisiana, 1965, M.D.

Internship, Residency and Fellowship:

Rotating Internship, Tulane Division, Charity Hospital, New Orleans, Louisiana, 1965-66.

Residency in Internal Medicine, Tulane Division, Charity Hospital, 1968-70.

National Institute of Health Fellowship, Pulmonary Disease, Tulane University School of Medicine, New Orleans, Louisiana, 1970-1972.

Military:

United States Public Health Service, Surgeon (Lieutenant Commander), assigned as Tuberculosis Control Officer, Jefferson County Health Department, Birmingham, Alabama, 1966-1968.

Previous Appointments:

Director, Bureau of Tuberculosis Control, City of New Orleans Health Department, New Orleans, Louisiana, 1970-1973.

Assistant Clinical Director, Charity Hospital of Louisiana, New Orleans, Louisiana, 1971-1972.

Tuberculosis Control Officer, Charity Hospital of Louisiana, 1971-1973.

Director, Inhalation Therapy, Charity Hospital of Louisiana, 1971-1973.

Director, Respiratory Intensive Care Unit, Charity Hospital of Louisiana, New Orleans, Louisiana, 1971-1973.

Assistant Professor of Medicine, Tulane University School of Medicine, New Orleans, Louisiana, 1972-1973.

Assistant Professor of Medicine, University of Alabama School of Medicine, Birmingham, Alabama, 1973-1975.

Medical Director, Bureau of Communicable Diseases, Jefferson County Health Department, Birmingham, Alabama, 1973-1978.

Associate Professor of Medicine, University of Alabama School of Medicine, Birmingham, Alabama, 1975-1979.

Chief, Pulmonary Disease Section, Veterans Administration Medical Center, Birmingham, Alabama, 1973-1985.

Current Appointments:

Professor of Medicine, University of Alabama School of Medicine, Birmingham, Alabama, 1979-present.

Assistant Dean/Education, University of Alabama at Birmingham, Birmingham, Alabama, 1976-present.

Associate Chief of Staff for Education, Veterans Administration Medical Center, Birmingham, Alabama, 1976-present.

Tuberculosis Coordinator, Alabama Department of Public Health, 1973-present.

Consultant, Bureau of Communicable Diseases, Jefferson County Health Department, Birmingham, Alabama, 1978-present.

Director, Comprehensive Asthma Program, University of Alabama at Birmingham, 1982-present.

Director, Lung Health Center, University of Alabama at Birmingham, 1986-present.

Member, NHLBI Task Force on Research and Education for the Prevention and Control of Respiratory Diseases, June 1988-present.

Member, NHLBI Expert Panel on the Management of Asthma, 1989-present.

Recipient, NHLBI Preventive Pulmonary Academic Award, 1989-1994.

Chairman, NHLBI Task Force on the Prevention of Asthma.

Member, National Heart, Lung, and Blood Advisory Council of the National Institutes of Health, 1991-present.

Member, UAB AIDS Center, 1992-present.

Professional Certifications:

American Board of Internal Medicine—Certification, Internal Medicine, 1972.

American Board of Internal Medicine—Certification, Pulmonary Disease, 1972.

Professional Associations and Committees:

Alabama Public Health Association—Chairman, Section on Tuberculosis, 1976-1977.

Alabama Thoracic Society—President, 1975-1976.

American College of Chest Physicians—Fellow.

American College of Chest Physicians, Steering Committee on Pulmonary Infection, 1976-1979, 1981-1984.

American College of Physicians—Fellow.

American Federation for Clinical Research, 1985.

American Lung Association of Alabama—President, 1987-1989.

American Lung Association of Alabama—Director-at-Large, 1983-1989.

American Medical Association.

American Public Health Association.

American Thoracic Society—Chairman, Tuberculosis Scientific Assembly, 1976-1977.

American Thoracic Society—Planning Committee, 1977-1978.

American Thoracic Society—Council, 1976-1980.

American Thoracic Society—Executive Committee, 1977-1980.

American Thoracic Society—Representative to the International Union Against Tuberculosis, 1981-present.

American Thoracic Society—Chairman, Scientific Assembly on Microbiology, Infectious Disease and Tuberculosis, 1983-1984.

American Thoracic Society—Alabama Representative to the Council of Chapter Representatives, 1982-87.

American Thoracic Society—Board of Directors—1983-1985; 1987-1990.

American Thoracic Society—Chairman, Council of Chapter Representatives, 1986-87.

International Union Against Tuberculosis—Committee on Epidemiology and Statistics, 1979-1986.

International Union Against Tuberculosis—Member, Governing Council, 1982.

International Union Against Tuberculosis—Committee TB Control, 1986-present.

International Union Against Tuberculosis—Secretary of TB Control, 1986 Jefferson County Medical Society.

Jefferson-Shelby Lung Association—Board Member, 1975-1978, 1980-1984.

Medical Association, State of Alabama.

Southern Medical Association—Committee on Publications and Journal Advertising, 1981-1982.

Veterans Administration Central Office Pulmonary Disease Consultant Advisory Committee.

Veterans Administration Pulmonary Physicians' Association—Secretary-Treasurer, 1982-1984.

Veterans Administration Pulmonary Physicians' Association—President-Elect, 1984-1985.

NHLBI Lung Health Study Steering Committee, 1984-present.

Veterans Administration Pulmonary Physicians' Association—President, 1985.

Veterans Administration Southeastern Regional Medical Education Center Program Review Committee.

Veterans Administration Medical Center's Official Representative, AAMC Group on Medical Education, 1987.

UAB Scheduling, Appointments, and Registration Committee, 1990-1991.

UAB Graduate Medical Education Committee, 1990-present.

VA Dean's Committee, 1990-present.

UAB School of Medicine Continuing Medical Education Committee, 1991-present.

Joint Health Sciences Faculty Status Committee, 1991-present.

Centers for Disease Control National Coalition to Eliminate Tuberculosis, ACCP Representative, Steering Committee member, Executive Committee member, 1992-present.

UAB Department of Pastoral Care Advisory Board, 1992-present.

PUBLICATIONS

William C. Bailey, M.D.

1. Bailey, William C.: Discussion of a Portable Device That Allows Emergency Cardiopulmonary Resuscitation to be Performed by One Person. Bulletin of the Tulane Medical Faculty 24:291-296, August 1965.

2. Bailey, William C., Thompson, Doris H., Greenberg, Harry B.: Mycobacterial Infections Among Poor Pregnant Women in New Orleans. The Journal of the Louisiana State Medical Society 124:237-240, July 1972.

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ABSTRACTS

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[Plaintiff's Exhibit #2]

THE HEALTH CONSEQUENCES OF SMOKING

CANCER AND CHRONIC LUNG DISEASE IN THE WORKPLACE

a report of the Surgeon General

U.S. Department of Health and Human Services
Public Health Service
Office on Smoking and Health
Rockville, Maryland 20857

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TABLE 5.—Comparison of smoking habit data obtained during life and after death

Smoking habit data obtained during life, 1971	Number	Smoking habit data obtained at death			
		Never smoked	Formerly smoked	Smoked	Smoked at some time
Never smoker	12	8	2	2	0
Ex-smoker	26	2	15	2	7
Smoker	76	1	12	33	30

SOURCE: Berry et al. (1985).

* * * *

[Plaintiff's Exhibit #3]

Reducing the Health Consequences of Smoking

25 YEARS OF PROGRESS

a report of the Surgeon General

1989

U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control
Center for Chronic Disease Prevention
and Health Promotion
Office on Smoking and Health
Rockville, Maryland 20857

* * * *

TABLE 11.—Estimated attributable risks for 10 selected causes of death from cigarette smoking, males and females, United States, 1985

Cause of death	Males (%)	Females (%)
CHD, age <65	45 (40-50)[a]	41 (34-48)
CHD, age ≥65	21 (17-26)	12 (9-15)
COPD	84 (78-88)	79 (73-83)
Cancer of lip, oral cavity, and pharynx	92 (79-97)	61 (45-76)
Cancer of larynx	81 (57-93)	87 (56-97)
Cancer of esophagus	78 (62-89)	75 (57-87)
Cancer of lung	90 (88-92)	79 (75-82)
Cancer of pancreas	29 (18-43)	34 (25-44)
Cancer of bladder	47 (31-63)	37 (18-61)
Cancer of kidney	48 (32-64)	12 (3-43)
Cerebrovascular disease, age <65	51 (36-65)	55 (45-65)
Cerebrovascular disease, age ≥65	24 (16-35)	6 (2-14)

NOTE: Computed from Tables 2, 6, and 7. For adult men under 65, the proportions of current and former cigarette smokers in 1985 were, respectively, 34.7 and 25.8 percent. For men 65 or older, the prevalances of current and former cigarette smoking were, respectively, 19.4 and 51.1 percent. For adult women under 65, the corresponding proportions were 30.1 and 16.5 percent; for adult women 65 or older, 12.6 and 19.6 percent.

[a] Numbers in parenthesis are 95-percent confidence intervals

* * * *

TABLE 18.—Estimated risks of various activities

Activity or cause	Annual fatalities per 1 million exposed persons
Active smoking	7,000[a]
Alcohol	541
Accident	275
Disease	266
Motor vehicles	187
Alcohol-involved	95
Non-alcohol-involved	92
Work	113
Swimming	22
Passive smoking[b]	19
All other air pollutants[b]	6
Football	6
Electrocution	2
Lightning	0.5
DES in cattlefeed	0.3
Bee sting	0.2
Basketball	0.02

NOTE: Activities are not mutually exclusive; there are overlaps between categories. Differences in fatalities do not imply proportionate differences in years of life lost.

[a] Number of deaths per million smokers who began smoking before 1965.

[b] Cancer deaths only.

SOURCE: Active smoking, CPS-II; NHISs 1965, 1985; U.S. Bureau of the Census (1974, 1986). Other activities causes, U.S. resident (1987).

* * * *

[Plaintiff's Exhibit #4]

THE HEALTH CONSEQUENCES OF SMOKING FOR WOMEN

a report of the Surgeon General

Prepublication copy: This copy is issued preparatory to printing as a formal document and is subject to editorial change. It omits an index which will appear in the final issuance.

U.S. Department of Health, Education and Welfare
Public Health Service.

* * * *

TABLE 8.—Histologic Types of Pulmonary Cancers in Smokers and Non Smokers

		Male		Female	
Type	Total	Smokers	Non-Smokers	Smokers	Non-Smokers
Epidermoid	992	892	7	80	13
Small Cell	640	533	4	100	3
Adenocarcinoma	760	492	39	128	101
Large Cell	466	389	16	46	15
Bronchioloalveolar	68	35	4	13	16
TOTAL	2,926	2,341	70	367	148

SOURCE: Resenow and Carr (39).

* * * *

[Plaintiff's Exhibit #5]

OBS	Name	Hosp. No.	Age	Histlogy	Pri. Site	Sur-gery	Sur-gery
1		89-48-85	34	8430	1623	1	5
2		00801382	37	8140	1629	0	2
3		00818283	38	8481	1623	1	8
4		00740064	36	8140	1623	1	3
5		00861339	35	8140	1623	0	1
6		00866553	36	8070	1622	1	8
7		00864742	39	8140	1623	1	8
8		00883227	38	8070	1623	1	5
9		00902963	29	8070	1629	0	0
10		00882055	38	8070	1623	0	0
11		00921916	38	8070	1623	0	1
12		00940420	29	8070	1623	0	0
13		00958265	28	8250	1623	0	1
14		00596419	38	8140	1624	1	5
15		01001846	38	8070	1623	1	8
16		00549551	32	8310	1623	1	5
17		00549551	32	8310	1623	1	3
18		01039428	38	8012	1623	1	5
19		01014568	37	8070	1625	0	0
20		00698307	37	8041	1622	0	0
21		01061452	32	8010	1629	0	1
22		01092377	37	8430	1629	1	7
23		01092439	33	8070	1623	1	5
24		01142091	33	8240	1624	1	5
25		01154179	37	8070	1623	1	5
26		01128174	38	8010	1625	0	0
27		01161962	31	8140	1625	1	3

Lung/Bronchus

0 None
1 Biopsy Only
2 Exploratory/Palliative
3 Partial Lobe Resection
4 Segmental Lobe Resection
5 Lobectomy
6 Pneumonectomy, Nos
7 Radical Pneumonectomy
8 Surgery, Nos
9 Unknown

Surgery variable

0 = no surgery
1 = surgery at UAB

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

EXAMINATION BEFORE TRIAL of the Defendant, GENERAL ELECTRIC COMPANY, taken by and through its representative, THOMAS O. ROUSE, held at the Desmond Americana, Albany-Shaker Road, Albany, New York on July 27, 1993, commencing at 9:10 a.m.; before Paula M. Marcucci, a Shorthand Reporter and Notary Public in and for the State of New York.

* * * *

[3] THOMAS O. ROUSE

having been first duly sworn by the Notary Public, [4] was examined and testified as follows:

* * * *

Q What is your professional address?
A General Electric, 100 Woodlawn Avenue, Pittsfield, Massachusetts.
Q You are manager of dielectric projects?
A Yes.

* * * *

[7] Q If you began work for GE in 1960, would it be fair to say that this has been your only full-time work as an adult?
A Since I left graduate school, yes.
Q And you went into graduate school fairly immediately after college?
[8] A Yes.

Q And you went into college fairly immediately after high school, or did you go in the service—

A No.

Q —directly after high school?

So that, has there been any other outside income after your PhD program was finished?

A Not for me personally.

* * * *

[9] Q When did you first have any knowledge, in your personal or professional capacity, of the use of PCBs as dielectric fluids?

A On my arrival in Pittsfield in April of 1973, when I left Corporate Research and Development and joined the transformer business.

* * * *

Q In the late '70s?

A The point I was getting at, about 99 percent of dielectric fluid used in transformers in the U.S. and the world is mineral oil.

* * * *

[13] Q When you first became involved, then, with the PCBs, they had already been terminated as an askarel or dielectric fluid by General Electric; is that right?

A No, General Electric stopped using PCBs in dielectric fluids around 1977—from '73 to '77. As I indicated, I was involved not as a primary activity, but I was involved with the search for substitutes in a peripheral way.

* * * *

[21] Q Do you know when General Electric first began to use PCB containing askarels?

A It's my understanding that was 1934.

* * * *

Q Why use PCBs containing askarel as opposed to non-askarel mineral oil dielectric fluid?

A It was found that PCBs do not burn easily and so in transformers they were used for that nonflammability application. That means, then, in transformers where a fire was a particular—could present a particular hazard if it began, askarel transformers were frequently used. Askarel filled transformers—and, as a matter of fact, the National Electric Codes list askarel transformers as one of the alternative ways of providing transformers in such areas, these are typically substations such that they are enclosed in buildings. They would be the basements of buildings such as hospitals, other areas of other buildings of [22] considerable concern. They had been used in manufacturing plants such as aluminum electrorefining plants, and they've been used in underground applications where the electrical network extended under the streets of a street; for example, Manhattan.

Q Is there any need for the use of an askarel transformer if the utility has no particular problems with space? Doesn't have any high-rise buildings, doesn't have any underground lines, doesn't have any electric furnace, that the transformer can't be put out at the back of the lot?

A There is no particular need that I'm aware of. Askarel transformers did develop an excellent service record, and I am told they've been used in areas where flammability was not at issue but the attempt to repair or replace would be difficult phyically so they've been used in applications where low maintenance, high reliability are of a particular interest.

Q With respect to the internal parts of transformers, let's take two transformers side-by-side, the kind that are mounted on telephone poles. Is there any difference between one that would be filled with [23] mineral oil and one that would be filled with askarel?

A I'm not aware of any pole mount transformers that were filled with askarel, but to the extent that there was—

Q Let me change my question, then. Let's say a small substation where there are, on the ground, the transformers of the size of a large refrigerator.

A To the best of my knowledge, there is no difference in the design of the cores and coil structure. There may be some difference in the external casing for the heat exchange surface, but the coil and core structure are often identical.

Q And does the use of an askarel allow the transformer, assuming identical core structures, to be rated higher than a mineral oil transformer with that same coil structure?

A I will give you my opinion about this as a chemist. I am not an engineer. . . . It is my impression that askarel transformers are usually less highly rated than oil filled because the askarel is a higher viscosity and poor transfer [24] medium. It is further my impression that askarel transformers less readily withstand very abrupt changes in voltage, and so they are used in areas where there is greater protection against lightning, more carefully rated switch gear, switch gear that would protect the transformer from unusual voltage surges. So, in general, I think it is my impression, as a non-engineer, that askarel transformers are used perhaps in more delicate roles than are oil filled transformers.

Q How do askarel transformers compare to dielectric vented or dielectric sealed transformers?

A Again, it is my impression that dielectric transformers offer very little overload capability. Transformers are frequently bought, I believe, on the basis of their name plate rating. That is, they are rated to be able to handle a certain kVA on a continuous basis. In many cases, a transformer purchased on that basis will, in the summertime, for example, have to handle a high air conditioning load and so it will be overloaded. It will be loaded a value higher than its name plate rating for some

relatively short periods of time. Oil filled transformers have a greater heat transfer capability, [25] and therefore they are better able to take those relatively short, heavy loads in excess of their design, their average design load. In doing that, they may be loaded to 150, 175 percent of their regular load. Dielectric transformers, as I understand it, do not, if very little, have any overloading capability. So, if you put a dielectric transformer into the same action as the oil filled transformers with those loads, you would either have to build one twice as big and let its unused capacity sit there the rest of the year, or sit there, or buy two.

Q When these mineral oil transformers are running at above-normal capacity, you mentioned the heat transfer capabilities. How hot do they get inside?

A Typical temperature inside, at the hot spot inside the coil, will be 100-110.

Q Degrees—

A Centigrade. Degrees centrigrade.

Q Get as hot as 180 degrees centigrade?

A Under extreme overload, and in some special applications where high power capability is required, yeah, as high as 180 might be reached.

* * * *

[28] Q What is the problem with oxidation?

A Problem with oxidation?

Q Yes, sir.

A Mineral oil is a mixture of hydrocarbon refined products, petroleum products, like motor oil, in that sense, and on the in-service, it tends to form, on oxidation, acid and sludge.

Q So, the lower the propensity to oxidate, the lower the the propensity to have acid and sludge?

A Yes.

Q Is PCB, in any of its congeners, an appropriate additive to mineral oil?

A Not that I know of.

Q Does it belong in mineral oil, dielectric fluids?

A It is not intended to be in any. General Electric uses, as a matter of fact, in the ASTM and in your local internal GE specifications there is a maximum of two parts per million PCB allowed. So, in a sense, the specification says there shouldn't be any measurable amount of PCB in the mineral oil.

* * * *

[29] Q Does PCB in mineral oil serve any beneficial purpose?

A PCB in mineral oil?

Q Yes, sir.

A Not that I'm aware of.

* * * *

[33] Q Do PCDDs have any place in mineral oil transformers?

A They should not. I am not aware of any finding that suggests PCDDs are formed by the chlorination of any of the hydrocarbons in transformer oil.

Q How about PCDFs?

A I am not aware of anything that should involve the chlorination of the hydrocarbons in mineral oil for PCDFs. On chemical grounds, I would think it even less likely.

Q With respect to PCDFs and PCDDs, do they serve any useful purpose when contained in a dielectric fluid?

A I'm not aware of any.

* * * *

[38] Q Do you know what level, what percentage of mineral oil transformers could be expected to have some level of PCB contamination?

A It has been estimated, in approximately 1988 or '89, that there was some 35 odd mineral oil containing—35,000,000 odd mineral oil containing transformers in service in the U.S. My recollection of that same study indicated that there was some 2,000,000 thought perhaps

to contain measurable quantities of PCBs and some 200,000 of those to contain in excess of 500 parts per million PCBs.

* * * *

[40] Q And do you know the results of that test?

A It is my impression that there were, on occasions, PCDF concentrations in nanograms per gram—

Q That's parts per trillion?

A Yeah. [No. Parts per billion.]

—found in some samples that were tested elsewhere under that program.

Q How about PCDDs in mineral oil?

A I do not recall whether there was a finding of PCDDs in those samples.

Q Can PCDFs be formed from PCBs—

A Yeah.

Q —and trichlorobenzene in askarel fluids?

A Your question was can PCDFs be formed?

Q Yes, sir.

A PCDFs have been found to be formed from the partial oxidation of PCBs. It is conceivable, but I would think extremely unlikely, for PCDFs to be formed from partial oxidation from chlorobenzenes.

Q Does the existence of mineral oil affect in any [41] fashion the likelihood of the formation of PCDFs from PCBs?

A Mineral oils are hydrocarbons that are relatively easily oxidated; which is gasoline or diesel, lower molecular weight materials. They, if vaporized with PCBs, will be partially oxidized and will be competing for the oxygen that is available; compete in a statistical sense. And so the amount of partial oxidated PCBs that go on will be decreased by the presence of the hydrocarbons surrounding them in a vapor base.

Q Which is a more successful molecule at picking up the oxygen needed to oxidize? The PCB molecule that needs one oxygen that would become a PCDF or the hydrocarbon molecules in the mineral oil that needs

multiple oxygens to become on fire or whatever is happening to it?

A Well, hydrocarbons are relatively much more easily oxidated than are PCBs; that's why they're commonly used as fuels in cars and furnaces, and so I would think that, as an example, transformer oil has a minimum flash point of 135-145, ASTM and in your GE specifications. That's the temperature in a particular test of geometry at which vapor from the [42] transformer oil is ignited. PCBs do not have a flash point, at least a higher molecular weight. PCBs do not have a flash point.

Q But what temperature do you understand the PCBs will begin to burn?

A I do not know.

Q These are PCBs chlorinated in the range that is used in askarels.

A I do not know any temperature at which they will begin to burn. The lowest temperature which I have seen in the literature reported in their formation—for the formation of PCDFs in the range of three, three-twenty centigrade.

MR. COCHRAN: 300 to 320?

THE WITNESS: 300 to 320 centigrade, which would be to 575 Fahrenheit.

Q With the maximum conversion current, around 600 centigrade?

A 550 to 600 degrees centigrade, I believe, is what the literature said.

* * * *

[47] THE WITNESS: This had to do with the estimated number of transformers in the country and the estimated population of transformers contained in a 50 to 500 parts per million. In August of 1989 there was a report written to EPRI entitled "PCBs Residue Transformer Carcasses." It was prepared by GE Pittsfield, and I authored it. As part of that work there was a survey conducted by the Research Planning Corporation a firm down in Washington, attempting to the estimate of numbers of transformers in service and the earlier numbers I gave you were in an attempt to reproduce the results of that study and were garbled a little bit. The studies conducted and published in 1989 estimated that [48] there were 20,000,000 mineral oil filled transformers in the country. There were 2,000,000 units containing 50 to 500 parts per million PCB estimated in service, and there were 220,000 units with greater than 500 parts per million. I think in my earlier comment I said something about 32,000,000 transformers, and I believe that's the number that's about right for today, 1993, for the total population, and since 1993 I would think that the number of units containing PCBs has decreased somewhat, as you would, pulled from service and not replaced or replaced with transformers, the units are replaced with transformers which do not have traces of the PCBs in them.

* * * *

[49] Q So, instead of the rough estimate we talked about earlier, 1 in 16, it's closer to 1 in 10?

A That's their estimate, yes.

Q And you think that sounds like a fair estimate?

A I'm sure they knew what they were doing in 1988. As I indicated a minute ago, I suspect that as older transformers are replaced in service, the number of transformers that contain traces of PCBs has gone down since replacement. New transformers do not have PCBs in them. I would think the numbers are somewhat lower today.

Q And the last date of potential contamination would have been 1977 when the industry stopped making PCB askarel transformers?

A Yes, and the regulation controlling the manufacturer [50] went into effect in '78. I'm sure there was action before that by the manufacturer.

* * * *

[60] Q How do PCBs get in mineral oil dielectric fluids?

A There are clearly several alternatives. One is that the oil used to fill transformers in manufacturing plants, mineral oil, is contaminated in some way by PCBs. A second is that the oil used to fill the oil—used for filling large transformers in the [61] field could contain PCBs, and many ultilities buy oil directly for use in transformers in their system and that oil might come from a refiner of new oil; it might come from small companies which took used oil from various sources, cleaned it up and resold it. And as a subcategory of that, many particularly large refineries have in their yards oil treating systems for clean up of oil which they will reuse, cleaned up oil that's generated in their system and will reuse it; be returned to use in transformers.

* * * *

[66] Q At what stage in that process do you believe the mineral oil transformers became contaminated with the PCBs?

A In those cases where mineral oil filled transformers were filled with oil containing PCBs, I would think that, in general, it would have come from contamination by the oil itself—of the oil itself by PCBs.

Q And where would the oil become contaminated in the process of its handling?

A The plant in Pittsfield is nearly 100 years old; was nearly 80 years old when it went out of business. The manufacture, the time period that Pyranol transformers, Pyranol, was used, involved some pipes; oil involved some pipes. Manufacturing capabilities moved around the plant through that time. It could have been contamination in the pipes when they hooked up that; had briefly been used to Pyranol, presently hooked up for use with oil. Could have been a case in which there was an inadvertent interconnection for some period of time. The storage areas for the two fluids were in the same vicinity near

the railroad or truck unloading site. It seems unlikely that there was ever a misunloading, but that can't be ruled out. [67] Transformers are filled and drained for various purposes. A transformer could be inadvertently filled with askarel and drained into an oil line; equally so, a transformer could be inadvertently drained with oil and drained into the Pyranol line. There is no intention to do this sort of thing because Pyranol is considered, I believe, more expensive than oil, so it's a relatively precious commodity. Oil defeats the nonflammability aspect, character, of Pyranol, and Pyranol defeats the economics of use of oil; oil means that you're adding a higher cost fluid to a lower cost fluid to no purpose. So, in all cases these kinds of actions of mixing were unintentional.

* * * *

[82] THE WITNESS: Okay. APC who were the contractors on this report, this section of the report, estimated 28,000,000 transformers, mineral oil filled transformers in 1982, 3,000,000 of them were in the 50 parts to 500 parts per million category, and 305,000 were in the greater than 500 parts per million category.

MR. COCHRAN: Thank you.

THE WITNESS: That's 1982.

* * * *

[84] Q Could it happen?

A Formation of PCDFs in oil filled transformers for PCBs?

Q Yes, sir.

A I would think it extraordinarily unlikely.

Q Could it happen if it's hit by lightning?

A I would think that quite unlikely.

Q Happen if it catches on fire?

A If there is combustion of the fluid or the fluid vapor, certainly.

Q Can it happen if it's heated with lamps, 3000 watt football field lamps?

* * * *

A The experiments that are reported in the literature, at least were reported rather exhaustively in the literature to the mid '80s, indicated that the formation of PCDF from PCBs was only—could be found only in temperatures in excess of 300 degrees—

[85] Q Centigrade?

A —centigrade; 300-320, in that. The boiling point for mineral oils is around 290 centigrade for the point—the transformer oil—boiling point for a transformer is around 290. There is a very substantial amount of organic vapor that, in any gas over liquid, that may be containing a small amount of PCDF which would have combusted readily and statistically would use up oxygen in place of its availability for PCDFs formation. In addition, as I indicated earlier, there is about as much paper in the coil as there is oil, and it seems to me very unlikely that paper would survive temperatures of 300 degrees without charring, blacking, so if it is a question of heating the liquid alone, I would think it unlikely and certainly if it's a question of heat coil system involving both solid and liquid in solution.

Q If the PCBs are in solution with the mineral oil, as the mineral oil boils off first, vaporizes first, would the remaining PCBs—would the remaining oil be rich in PCBs or leaner in PCBs?

A The boiling range for mineral oil runs from around 290 to around 450-500 centigrade. The boiling range [86] for PCBs is really not too far different from that, but the boiling range, as I recall it, for 1260 Aroclor is somewhat higher than that. Therefore, I would think there is some possibility of a distillation separation occurring. If I can reiterate something I said earlier, if the insulation system involving paper is involved in that, I think

you would have other processes going on other than simple distillation.

Q Any of those processes create PCDDs?

A The charring of paper is not going to create PCDDs or PCDFs. It will create an unusable coil.

Q Can PCDFs be created and—PCDDs, I'm sorry, be created in a PCB contaminated transformer, meaning for my question, less than 1000 parts per million in mineral oil as a result of any foreseeable lightning strikes, fire, excessive heat, electrical arcing?

A There is no evidence that PCDDs are created from PCBs under any conditions.

* * * *

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

EXAMINATION BEFORE TRIAL of a the DEFENDANT, GENERAL ELECTRIC COMPANY, through an expert witness, DR. JOHN BROWN, conducted pursuant to the Federal Rules of Civil Procedure, before Lillian M. Cunniff, a Shorthand Reporter and Notary Public in and for the State of New York, held at the Desmond Americana, Albany-Shaker Road, Albany, New York, on Monday, July 26, 1993, commencing at approximately 12:30 p.m.

* * * *

[6] DR. JOHN F. BROWN, JR.

called by the plaintiff, having first been duly sworn by the Notary Public, was examined and testified as follows:

* * * *

[7] Q. What is your present occupation?

A. My present occupation is Manager of Health Research at the named organization, General Electric Corporate Research and Development.

Q. How long have you been with General Electric?

A. Since 1950.

* * * *

Q. Give us the benefit of your education which enables you to serve in your present capacity?

A. I received a Bachelor's degree, a B.S. in Science in chemistry from Brown University in 1947; a Ph.D., also in chemistry, from MIT in 1959; and many years later, 1968 to 1969, took a post doctoral fellowship in clinical

pathology at the Upstate Medical Center in Syracuse, New York.

[8] Q. Other than that stint in clinical pathology, have you had any formal training in medicine?

A. No.

Q. What was your doctoral thesis concerning?

A. The title was "Polyfunctional Catalysis," which was concerned with the development of synthetic chemical models for biological enzymatic processes.

Q. Is that in any way relevant to our discussion today concerning PCB's—the effect of PCB's on human health and the analysis of the existence of PCB's in human adipose tissue. And when I say PCB's, I have included known contaminants, such as PCDD's and PCDF's.

A. Only to the extent that my thesis was concerned with the rates and mechanisms of chemical reaction. And after many years of research on diverse subjects, I have been concerned with, among other things, the rates and mechanism of clearance of PCB's from the human body and the information they provide as to the mechanisms of a body's response to the PCB's.

Q. What other major papers—papers that you would consider major—have you been involved in preparing as an author? Do you maintain a list of those, by the way?

A. Yes. I have written about 60 technical papers.

Q. How many of those relate to PCB's?

[9] A. Most of those written in the past dozen years.

* * * *

[21] Q. What is a PCB?

A. PCB stands for polychlorinated biphenyl. It's a set of initials that did not come into use until the late 1960's, and was not so designated until earlier. It can refer either to the family as a whole, or one of the individual commercial products, or to one of the individual chemical components of one of those products.

Q. Let's talk about the chemical individual first, and then we can break it down into the other topics you mentioned. How many congeners of PCB do you recognize?

A. 209.

* * * *

[24] Q. Do you believe there is any association between PCDD and PCB; that is, a PCB in any fashion—sunlight, aging, fire—anything that can convert PCB's to PCDD's?

A. I do not believe so.

Q. What about PCDD's from other ingredients in commercial askarels; for example, Pyranol has—tricholorobenzyne is a major constituent, about 40 percent of that; correct?

A. Yes.

Q. Can PCDD be formed from the askarel mixture which includes tricholorbenzynes through fire, aging, sunlight, or any other action of which you are aware of?

A. Yes. I am aware that there have been scientific reports of the conversion of chlorobenzynes to trace quantities of PCDD's at high temperatures.

Q. Do you know what temperature is necessary to make that conversion occur?

A. I do not know what is reported in the literature on that conversion, no.

Q. Does that make scientific sense to you, not just that you have read it, but does it make scientific sense to you that, yes, indeed PCDD's can be caused to come into [25] existence from a commercial askarel mixture under certain circumstances?

A. Yes. But it would depend on what else the askarel was mixed with. If the askarel was mixed with transformer oil, this would become much less probable.

Q. Transformer oil, meaning standard mineral oil used in transformers?

A. Yes.

Q. Why is that?

A. Because the oxidation of a chlorobenzyne to dioxin involves the capture of reactive oxygen fragments in the flame formed at high temperature. And these would be much more easily captured by hydrocarbon molecules than chlorobenzyne molecules.

* * * *

[26] Q. [. . .] What do you consider the most commonly and widespread PCDD congener that you know?

A. The most widespread PCDD congener is octachloro dibenzo dioxin, which is a fairly common combustion product.

Q. Combustion of what?

A. Of any organic material containing any chlorine compound.

Q. Including PCB's?

A. Including salted wood.

Q. But I need you to answer the first question. It does include PCB's; is that correct?

A. Yes.

* * * *

[31] Q. But does that make scientific sense to you, that if metal turns red hot and PCB's are on it or near it to gather its heat at close to 600 degrees centigrade, that those PCB's will begin to convert to PCDF's?

A. Yes, in the presence of oxygen.

Q. Does mineral oil—the existence of mineral oil affect this conversion rate as you described it affects, in your opinion, the conversion rate of PCDD's?

A. In my opinion, the mineral oil would inhibit PCB oxidation to dibenzo furan under any conditions.

* * * *

[38] Q. Do you believe that PCB's have any toxicity to human beings as contained in askarel dielectric fluids?

A. We have spent the last 16 years looking for such effects in people with heavy occupational exposure without finding any evidence of deleterious health effects.

Q. Do you not consider chloracne a deleterious health effect?

A. We do not believe that chloracne has ever been seen in people who were exposed to unaltered electrical grade PCB's.

Q. What is an alteration that you think would be necessary to electrical grade PCB's to cause them to give a human being chloracne?

A. Prolonged exposure to high temperatures of 300 degrees C.

Q. How long?

A. Days.

* * * *

[39] Q. When you decide to conduct a scientific experiment, do you prepare a protocol or a plan for doing so?

A. Not normally.

Q. Do you develop a question that needs to be answered or a hypothesis that needs to be proven of disproven?

A. Yes. I think it is essential to the nature of scientific investigation that one attempt to distinguish between alternative hypotheses as to the causation of the phenomenon, if any, being observed.

Q. So, eighth grade science students would be familiar with the idea of formulating the hypothesis that water freezes at 32 degrees Fahrenheit; and then, they would be about trying to prove that hypothesis. Is that an example of that procedure?

A. Yes. But the difference between professional research and eighth grade science experiments is that the [40] identification of the key hypothesis is very frequently a major portion of the research investigation to be conducted.

Q. And very frequently that identification is affected by the person financing the investigation; is that correct?

A. I would not say the identification, because the difference between scientific and advocacy procedures is

that basically in a scientific investigation, one is attempting to gather information to eliminate alternatives rather than argue for a particular hypothesis.

Q. But isn't it true that General Electric has never paid you to prove that PCB's are toxic, but instead has paid you to prove that PCB's are not toxic?

A. I have not received any instructions as to how this research—what the findings should be. My involvement in this program came at my initiative, not General Electric's, because I felt it was important to find out. It is also true that the people in the Capacitor Department who initiated the study were the plant hygienists, who was the nurse, and the physician who had a part-time job, whose major job was as a general practice physician in the community, who were very much concerned as to possible health effects on the people for whom they were responsible.

[41] Q. People for whom they would be responsible under worker's compensation statutes if, in fact, there was a causal effect between any illnesses suffered by these people and their job place exposure to PCB's; is that correct?

A. The orders that we got from—and on one occasion when we talked to the corporate medical director —were to find out what the problem was all about. They said they were fully prepared to pay workmen's compensation claims to people who needed that, who deserved them, but they were not interested in paying such claims to the entire population of Upstate New York. That's as far as our instructions went.

Q. Did your instructions as a researcher for General Electric also include voluntarily going to the Government and arguing with them about their classifications of PCB's as potential carcinogens, or suspected carcinogens, or whatever classification the Government thought was appropriate compared to with what General Electric thought was appropriate?

A. I have never been told what General Electric thought was appropriate. I initiated these—I proposed these research programs in 1976 and '77, and spent two years convincing the Company that it was a good idea to carry on health effects research.

Q. But isn't it true that the Company did, in fact, [42] have a significant role, non-scientist, within the Company, such as vice-presidents had a significant role in the words you used when you communicated with the Government in writing?

A. No.

Q. That was never approved?

A. As far as I know, the words that I have used that have appeared under my name were those that I selected and put into my reports.

* * * *

[48] Q. In fact, you have never come to a therapeutic modality to treat someone with high levels of PCB's; is that correct?

A. Nor has anyone else.

Q. So, there is no known treatment?

A. There are some procedures that can be used to reduce PCB levels to a modest extent, but these would be therapeutically unacceptable to the medical community, because in the absence of any medically convincing evidene of health effects associated with existing PCB body burdens, it would be medically improper for a physician to prescribe such a treatment.

* * * *

[49] Q. In other words, if you have a drastic weight loss, it's your opinion that the effect is to reduce the half-time?

A. No. The treatment—the therapeutic—the pharmacological intervention that caused the weight loss in [50] this case results in PCB removal. This is not the normal case. There is a considerable body of research on experimental animals indicating that weight loss normally

results in an increase in the concentration of PCB's in lipid reservoirs in the body.

* * * *

[52] Q. Do you believe that warnings advising people not to inhale, ingest, or absorb PCB laden materials are appropriate?

* * * *

A. Such warnings are routinely given regarding almost all chemical materials.

Q. Are they necessary with PCB's?

* * * *

[53] A. Probably much less so than with most other materials. The acute toxicity is known to be very low.

Q. Do you hold that opinion even with the knowledge that PCB's often are contaminated with PCDF's?

* * * *

A. The question is incorrect. PCB's are not often contaminated with PCDF's. It's very rare for them to be contaminated with significant levels of PCDF's.

Q. Would you agree with me that it is foreseeable that in such instances PCDF's will exist at some level in PCB products, such as Aroclors?

* * * *

A. I think I already testified that PCDF's can be found in electrical grade PCB's, at levels of from zero to two parts per million in what we have seen, and that these levels are toxicologically insignificant.

* * * *

[54] Q. Do you think that death is a risk of exposure to PCB's?

[55] A. No.

Q. Do you think that death is a risk of exposure to PCDF's?

A. The available evidence in both cases comes from statistical studies that have been done on people exposed to either PCB's or PCDF's. To my knowledge, such studies which involve analyses of death records have not shown any elevated mortality in the case of people exposed to PCB's, with quite large populations involved in the studies. So, the statistical power is considerable.

In the case of PCDF's, the number of deaths that have been looked at by the Japanese in their review of the Yusho poisoning victims is considerably more limited. It is my understanding that thus far Dr. Kuratsune, who has been the head of the Japanese investigative team, has been reluctant to ascribe any increased mortality to the people in the Yusho poisoning group.

* * * *

[64] Q. So, all of your responses on that are going to be based on the Triangle Laboratory reports, because we are going to ask about that in a little while.

A. Okay. Then, I will say based on my observation of the Triangle Laboratory reports, he showed a level and distribution of PCB's that was in the background range; in fact, below the normal environmental background—excuse me, below average environmental background.

* * * *

[86] Q. Is there anybody in General Electric, to your knowledge, who has written more published articles about PCB's than you?

A. Well, I have never made a publication count, but I'm not aware of one.

Q. Do you think that you would be considered to be the person at General Electric who knows as much about PCB's as anybody there?

A. Yes, about PCB science and some of its technological aspects. But I had no knowledgeability about anything involving commercial practices.

Q. We are going to come down to the home stretch. You have mentioned technological aspects; so, let's go right [87] into this Triangle Laboratory report. Have you reviewed that relating to Mr. Joiner?

A. I have not reviewed the details of the analytic methodology, because my colleague, George Frame, agreed to take on that assignment. What I did do was to examine the level and distributions of the PCB and PCDF congeners found to determine as best I could whether they were within a normal or abnormal range.

Q. And what did you discover?

A. What I found was that the levels of PCB's and PCDF's were both within the lower part of the range normally involved in environmentally exposed populations, that there were no obvious abnormalities that might have resulted from accelerated clearance, that the homologue distribution in the PCB's were again very similar to what we and many others have seen in background exposed populations.

* * * *

[94] Q. But it would be your opinion at any rate that even if he showed instead of .4 or .3 something parts per million of PCB's, even if he showed 1 part per million, that would not necessarily be causing him any problem; is that right?

A. I would guess that the average individual sitting in this room has more than one part per billion—

Q. I said million.

[95] A. Million.

Q. Would you guess that the average person in this room has more than one part per million?

A. Probably close to that.

Q. That would be 100 parts per billion; is that right?

A. One part per million—no, in adipose tissue.

Q What would that be per billion?

A. That would correspond to about five parts per billion in serum.

Q. What would 100 parts per million of adipose tissue correspond to in parts per billion adipose tissue? I'm not trying to quiz you on your math skills; I'm asking so that I will be clear.

A. Wait a minute; 100 parts per million in adipose tissue?

Q. Yes.

A. That's a pretty high level.

Q. Because you and I were talking apples and oranges. Somehow, I got lost in here. You switched serums of adipose on me in the middle.

A. There is a 200-fold difference between the two; that's the way to think about it on the average.

Q We discussed at Dr. Schector's [*sic*] deposition that [96] there are folks who believe that .4 parts per million in adipose tissue is within the normal background range.

A. Yes.

Q. Do you agree with that?

A. Yes.

Q. At what level would you start to have concern about someone's physical health, keeping the scale at parts per million and keeping the tissue at adipose?

A. I don't know that, because we have not seen effects in people who probably had adipose tissue levels as high as a thousand parts per million.

* * * *

[97] Q. There is no PCDF testing available for Mr. Joiner is there in what you have reviewed?

A. I recall there were PCDF analyses reported on him.

Q. What was your opinion as to those levels?

A. The levels and distributions again were within the range that has been reported for the American population, and even the pattern of non-detects reported corresponds to what has been reported for a natural range of background population.

Q. How about PCDD levels in Mr. Joiner?

A. They were also low. I did not check on the distribution of non-detects.

* * * *

[101] Q. Are you familiar with the work of Arnold Schector [*sic*] on the subject of PCB's?

A. Arnold Schector [*sic*] has written a hundred papers on PCB's and dioxins, mostly dioxins. I have not read all of them.

Q. Do you consider him to be authoritative; his [102] papers?

A. Just the papers?

Q. The ones that you have read, did you find them to be consistent with scientific knowledge and authoritative with something published in your line?

A. Where he has reported data on observed environmental levels, the results are as good as the laboratories doing the work. I have known Arnold Schector [*sic*] for quite awhile. I'm rather skeptical of his interpretations, as are many other people, and I would not regard his interpretations of the analytical data he has as scientifically authoritative.

Q. Why not?

A. Because he is clearly a man who has written more than he has read. He is just cranking out paper without thinking about it.

Q. Do you think he has a bias?

A. Sure. He is trying to justify his position with respect to the Binghamton State Office Building fiasco.

* * * *

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA

(Title Omitted in Printing)

DEPOSITION OF STEPHEN B. HAMILTON, JR.

* * * *

[4] STEPHEN B. HAMILTON, JR., 154 Driftwood Lane, Trumbull, Connecticut, 06611, having been duly sworn, was deposed and said:

* * * *

[5] Q I've got a copy of your CV here. What did you do your thesis on in your Ph.D. program at Northwestern?

A I did research on aromatic heterocyclic compounds containing boron.

Q Does that subject have any relevance, other than [6] the analytic techniques you have learned, to this particular finding—does that have any relevance to your present knowledge of PCBs?

A No.

Q And you did some post-doctoral research in Germany. Was there any relevance in that study of the PCB issue?

A No.

Q Have you published any papers on the PCB issue or anything related to PCBs?

A I've been a co-author on several papers regarding PCBs.

* * * *

[33] Q What is it about your education and employment [34] background which you believe qualifies you to tell me about the health risks of PCBs?

A I think it's that I've established myself as a scientific scholar, having gotten a Ph.D. in chemistry, am familiar with research techniques, and have devoted the last about 12 years of my career to this particular issue.

* * * *

[39] Q You mentioned the term biodegradability a little while ago. Let me ask you another term: Bioaccumulation. Does that concern you from an environmental point of view with respect to PCBs?

* * * *

[40] A Bioaccumulation is not a toxic effect per se. It merely reflects the tendency of certain chemicals like PCBs to partition into certain media.

Q Can it have a toxic effect?

A Pardon me?

Q Can it have a toxic result?

A If the chemical is toxic to that species, it may have a toxic result.

* * * *

[60] Q Do you think PCBs can cause lung cancer?

A Do I? No.

Q Why not?

A Well, there have been a number of epidemiological studies of PCB-exposed populations, people with very high exposure to PCBs, and we have not seen excesses of lung cancer among those populations. In fact, we've generally seen deficits in lung cancer.

Q Are you aware of various studies which have shown [61] increases in lung cancer but which were found to be statistically insignificant, but nevertheless existed?

A With PCBs? Where the principal exposure was PCBs?

Q Yes, sir.

A I don't recall off the top of my head. I'm aware that if you look at this body of literature in aggregate, there are not excesses. In fact, in a study of our plant that awas done by an investigator from Harvard, sponsored by NIOSH, he attempted to see if there was correlation between several different cancers and PCB exposure, and the correlations were negative. In one case statistically significant that dealt with all cancers, negative but not statistically significant for lung cancer. By correlation, being negative means as PCB exposure went up, the incidence of lung cancer went down.

Q How about with PCDFs, do you consider it possible to get lung cancer from exposure to PCDFs?

A I don't have any information on that other than to say that the workers in our studies were exposed to the totality of what was in the PCB mixtures, which presumably contained PCDFs.

* * * *

[87] Q Do you believe that PCBs can promote any kind of cancer cells at any location in human bodies?

A I don't think there's any evidence to suggest that—

Q How—

A —in humans.

Q How about PCDFs?

A There's a much smaller data base, but, again, I don't see positive evidence.

* * * *

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

EXAMINATION BEFORE TRIAL of a [] DEFENDANT, GENERAL ELECTRIC COMPANY, through an expert witness, DR. GEORGE FRAME, conducted pursuant to the Federal Rules of Civil Procedure, before Lillian M. Cunniff, a Shorthand Reporter and Notary Public in and for the State of New York, held at the Desmond Americana, Albany-Shaker Road, Albany, New York, on Monday, July 26, 1993, commencing at approximately 10 a.m.

* * * *

[4] DR. GEORGE FRAME,

called by the plaintiff, having first been duly sworn by the Notary Public, was examined and testified as follows:

* * * *

[6] Q. Am I correct in my understanding that your role here today is to testify concerning the adipose tissue testing done by Triangle Labs on adipose tissue of Robert Joiner?

A. Yes, sir.

Q. What is it about your education and training which you believe qualifies you to opine on this subject?

A. I have a Ph.D. in analytical chemistry from Rutgers University; I have worked subsequent to that for 25 years in analytical chemistry; I have specifically conducted PCB analyses by a variety of methods, including mass spectrometry both for other organizations as well as the General Electric Company.

Q. Let's talk about your education very briefly. Where did you attend college, sir?

A. My undergraduate college was Harvard College, Cambridge, Massachusetts.

Q. What was your major there?

A. Chemistry.

* * * *

[22] Q. With respect to this particular case, what do you understand the methodology used by Triangle Labs consisted of?

A. I understand it to have been a Triangle Labs specifically designed method using generally acceptable sample extraction, and preparation, and clean-up steps for adipose tissue, and subsequent analysis—depending on whether the analysis was for PCB's, or for the PCDF's, or PCDD compounds—by high resolution gas chromatography using as the detection method high resolution mass spectrometry. An additional feature of the analysis is the use of istotope labeled internal and surrogate standards.

* * * *

[23] Q. The test for PCB's on Robert Joiner's adipose tissue; what do you think that means? What was the result?

A. The material that was presented to me, and the summary tables of the analysis of polychloronated biphenyls, reports the data for a number of components. And I have looked at the way in which the data was obtained and the way in which it was presented, and I find nothing to criticize or to disbelieve about the quantities of PCB's that are reported.

I find that the design of the analysis specifically identifies a subset of individual PCB chemical [24] structures, which is, in fact, the set of isotope labeled internal standards which enable the analyst to determine and identify specific PCB's. The design of the analysis also detects other PCB congeners which may be present, and quantitates them against the isotope labeled internal standards, but does not specifically identify which congener they are.

The summary data of all the congeners which are detected and quantitated by the standards that Triangle Laboratories employs to determine that they have, in fact, detected and quantitated adequately a congener, when summed, produce a total PCB content detected by this method in this sample of 0.3 parts per million by weight of PCB's.

* * * *

[28] Q. Have you read any of his writings concerning PCB, PCDD, and PCDF levels in human adipose tissue?

A. No.

Q. Why not?

A. I have only heard his name very recently with respect to this case, and my involvement has been strictly to examine the material from Triangle Laboratories to determine if the analysis was performed properly. I have not become involved in the interpretation of the levels.

* * * *

Q. What do you think about Triangle Laboratory's levels of PCDD's found in Mr. Joiner's adipose tissue?

[29] A. I found nothing to criticize about the methods that were used. Clearly, looking at the summary table, most specific congeners that were analyzed were not detected above their limit of detection, but I found nothing in my study of the analytical levels to indicate that any error or improper analysis was done.

* * * *

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

DEFENDANTS' JOINT MEMORANDUM IN SUPPORT OF SUMMARY JUDGMENT

INTRODUCTION

Plaintiffs, Robert K. Joiner and Karen P. Joiner, contend that Mr. Joiner's alleged occupational exposure to low levels of polychlorinated biphenyls (PCB's)[1] while employed as an electrical transformer repairman caused his small cell lung cancer.[2]

At the heart of this toxic tort case is the threshold question of causation. In recognition of that fact, the parties agreed on a scheduling order that focused first on the issue of cauation and permitted the defendant to test, on a motion for summary judgment, whether the plaintiffs would be able to present (through admissible expert opinions) *prima facie* proof of causation sufficient to enable them to go forward with their claims. *See*, July 13, 1993 Order. Defendants, General Electric Company ("GE"),

[1] PCBs are man-made chemicals once used in a wide variety of industrial applications, including as an insulating fluid in electrical equipment.

[2] Small cell lung cancer is a certain type of lung cancer as distinguished from, for example, squamous cell lung cancer. According to one of the plaintiffs' experts, Dr. Larry Robertson, "there are a multiplicity of cancers arising from a number of different cell types, from a variety of different causes. That is general knowledge." (Robertson Depo., at 13).

Westinghouse Electric Corporation ("Westinghouse"), and Monsanto Company ("Monsanto"), submit this memorandum in support of their joint motion for summary judgment, on the following grounds:

SUMMARY OF ARGUMENT

In order to pursue a claim against these defendants, plaintiffs' hypothesize that Mr. Joiner's small cell lung cancer was caused by occupational exposure to PCBs. To support this hypothesis, the plaintiffs proffer the opinions of three "experts": Dr. Larry Robertson, Dr. Arnold Schecter and Dr. Daniel Tietelbaum. Although these experts admit that Mr. Joiner was a cigarette smoker and admit that cigarette smoke is a known cause of small cell lung cancer, the plaintiff's experts nonetheless attempt to link Mr. Joiner's small cell lung cancer to exposure to PCB's. Two of the plaintiff's experts state that Mr. Joiner's small cell lung cancer was "promoted" by PCBs after being "initiated" by cigarette smoke. A third expert states that cigarette smoke, PCBs, and various known carcinogens in Mr. Joiner's workplace combined in a "multifactorial mix" to cause Mr. Joiner's small cell lung cancer.

The plaintiffs' experts' opinions, however, are speculative, contradictory, hypothetical, unreliable, unhelpful, irrelevant and otherwise legally insufficient to provide plaintiff a prima facie showing on the issue of medical causation. The plaintiffs' experts' opinions fail for each of the following separate and independent reasons:

1. As admitted by plaintiffs' own experts, their opinions are not based on credible scientific evidence and are therefore "speculative."

2. The opinions are not supported by epidemiological studies. Epidemiological studies covering thousands of workers exposed to PCBs over several decades have not found any association between PCBs and lung cancer.

3. The opinions are based exclusively on isolated studies of laboratory animals. Laboratory animal studies, in and of themselves, are insufficient to constitute admissible evidence of causation in human beings because they are *not* reliable predictors of human health effects.

4. The opinions are based on erroneous facts and unfounded assumptions. The opinions did not "fit" the facts of the case, that is, they are not "sufficiently tied to the facts of the case". *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. ——, 113 S.Ct. 2786, 2796, 125 L.Ed.2d 469, 481 (1993).

5. The opinions assume Mr. Joiner absorbed PCBs at a significant level. In fact, Mr. Joiner has a PCB body level *below* that of individuals in North America who have never been *occupationally exposed to PCBs.*

Because the opinions of plaintiffs' experts do not constitute admissible evidence upon which plaintiffs can rely to support their hypothesis, the plaintiffs have failed to establish a prima facie case of medical causation. By failing to establish a causal link between PCBs and small cell lung cancer, the plaintiffs cannot maintain this action. The defendants are entitled to judgment as a matter of law and their motion for summary judgment should be granted.

* * * *

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

DEFENDANTS' STATEMENT OF MATERIAL FACTS

In accordance with Local Rule 220-5(b)(1), the defendants, General Electric Company, Westinghouse Electric Corporation, and Monsanto Company, submit this separate and concise statement of the material facts to which they contend there is no genuine issue to be tried. This statement is submitted in support of the defendants' joint motion for summary judgment.

1.

Robert K. Joiner has worked at The City of Thomasville Water & Light Department ("Thomasville Water & Light") since 1973.

2.

As part of his employment at Thomasville Water & Light, Mr. Joiner worked with and around electrical transformers and voltage regulators.

3

The dielectric fluid contained in the electrical transformers and voltage regulators used by Thomasville Water & Light was mineral oil.

4.

After Thomasville Water & Light began testing its mineral oil-filled equipment for the presence of PCB contamination in 1983, it determined that less than twenty percent of its equipment was contaminated with PCBs.

5.

Of all of the equipment tested by Thomasville Water & Light, only about 2.5% of the transformers tested contained levels above 500 ppm, while only about 16.7% of the equipment contained levels above 50 ppm.

6.

The EPA considers any electrical transformer containing less than 50 ppm of PCBs to be a "Non-PCB Transformer" and does not regulate such equipment.

7.

One (1) transformer at Thomasville Water & Light (not manufactured by either GE or Westinghouse) contained 1,880 ppm PCBs, which was the highest reported level for any transformer or voltage regulator.

8.

In 1991, Robert K. Joiner was diagnosed with small cell lung cancer.

9.

Mr. Joiner smoked cigarettes, and both of his parents smoked cigarettes while he was growing up in their home; thus, according to the plaintiffs' experts, Mr. Joiner had consistent, substantial exposure to cigarette smoke for many years.

10.

Small cell cancer of the lung in humans is caused by tobacco smoke.

11.

According to the plaintiffs' own experts, there is no credible evidence as a scientific probability that PCBs cause or promote small cell lung cancer in humans.

12.

According to the plaintiffs' own experts, there are no epidemiological studies which conclude that PCBs cause or promote small cell lung cancer in humans, or more generally, any form of lung cancer in humans.

13.

According to a labtoratory test of Mr. Joiner's adipose (fat) tissue obtained by Mr. Joiner in 1991 approximately four months after the diagnosis of his small cell lung cancer, Mr. Joiner's body level of PCBs was .3 ppm.

14.

Mr. Joiner's body level of PCBs, as measured in the analytical laboratory test of Mr. Joiner's adipose tissue, shows that Mr. Joiner's body level of PCBs was slightly less than the average individual in North America who has not had any occupational exposure to PCBs.

15.

None of the plaintiff's expert witnesses can quantify either Mr. Joiner's exposure to PCBs or his dose of PCBs.

This 8th day of December, 1993.

/s/ Anthony L. Cochran
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Attorney for Defendant
General Electric Company

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[Filed Jan. 31, 1994]

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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6. A PPM is More Than Enough to Kill.

Defendants' argument that Robert Joiner's exposure to PCBs was not significant, through their efforts to minimize the extent of their deadly chemicals, by analogizing the parts per million ("ppm") measurement with inches per mile, or pints per gallon, do not demonstrate the "vanishingly small nauture of a 'ppm' ". (Defendants' Brief at 4, fn 3) Instead, this demonstrates the incredible toxicity of these chemicals. A more relevant analogy is offered by Michael H. Brown, *The Toxic Cloud*, at pages 249-250. Mr. Brown writes that: "At about sea level there are approximately 10 billion trillion air molecules in a breath of air, or as many molecules as there are stars in the known universe. So one part per quadrillion, tiny as it seems, might translate into 10 million dioxin molecules in each breath."

The World Health Organization believes that "[n]o levels of PCBs . . . exposure that can provide an absolute assurance of safety can be identified on the basis of the available data." [86] No less an authority than the Administrator of the United States Environmental Protection Agency has concluded that "the concept of a threshold exposure level has no practical significance where carcinogens are concerned. This is due to in part to the irreversibility and long latency period of carcinogens." *Environmental Defense-Fund, Inc. v. Environmental Protection Agency*, 510 F.2d 1292, 1298 (D.C. Cir. 1975). Accordingly, there is no level of exposure which is not significant.[86]

[86] IPCS at 22.

* * * *

(2). The Testimony is Admissible Under Rule 104.

Rule 104(a) requires this Court to resolve "[p]reliminary questions concerning the qualification of a person to be a witness, . . . [and] the admissibility of evidence . . . ." Fed. R. Evid. Rule 104(a). Plaintiffs' experts are qualified and their opinions are admissible.

(a). Plaintiffs' Experts are Qualified.

The experts relied upon by Plaintiffs have impeccable credentials and are qualified to testify. Defendants have not seriously challenged their qualifications to testify.[84]

* * * *

[86] Put another way, no reasonable parent would ever intentionally allow their child to be exposed to any level of these chemicals if such exposure could be avoided.

* * * *

[84] Defendants have challenged Dr. Robertson's qualifications in some areas. This limitation is admitted by Dr. Robertson. Dr. Robertson's testimony, though relevant, is not necessary to defeat this motion. His testimony will assist the jury at trial.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

AFFIDAVIT OF DR. ARNOLD SCHECTER, MD, MPH

Personally appeared before me, the undersigned officer duly authorized to administer oaths, Dr. Arnold Schecter, who after being duly sworn, deposes as follows:

INTRODUCTION

1.

I am Dr. Arnold Schecter, MD, MPH., a competent adult, laboring under no disabilities.

2.

I make this Affidavit for any lawful use or purpose. I have personal knowledge of the facts set forth in this Affidavit.

3.

I reside at 88 Aldrich Avenue, Binghamton, New York, 13903. My professional address is Clinical Campus, College of Medicine, SUNY—Health Science Center Syracuse, 601 Gates Road, Vestal, New York, 13850.

EXPERTISE

4.

My current curriculum vita is attached to this affidavit as Exhibit "A" and it accurately reflects my training and experience in the fields of medicine, public health, and the effects of toxic chemicals, specifically polychlorinated biphenyls ("PCB"), polychlorinated dibenzofurans ("di-

benzofurans" also sometimes referred to as "PCDF"), and polychlorinated dibenzo-p-dioxins ("dioxins" also sometimes referred to as "PCDD") on human beings. My research and training includes study of these chemicals in human beings.

5.

I am a tenured full professor of preventive medicine at a major New York State medical school, and have been for over fourteen years. Before that, I was on the faculty at the New Jersey Medical School, SUNY Downstate Medical School and Harvard Medical School. I am board certified in preventive medicine and have been since 1976. I am a Fellow of the American College of Preventive Medicine, the American College of Physicians, and also the American Association of Occupational and Environmental Medicine.

6.

I am licensed to practice medicine in Kentucky, New Jersey and New York. I am on the staff of all three hospitals in my county. I see patients, but primarily do research now, on patients, the environment, and laboratory animals. My research is focused on the toxic effects of dibenzofurans, dioxins, and PCBs. I work full time in this field, and am one of the few American physicians to do so.

7.

I am a member of several national or international epidemiology scientific societies and am also a member of several toxicology societies. I have published over 100 papers relating to dioxins, dibenzofurans and/or PCBs since 1981. My writings concerning dioxins, dibenzofurans and PCBs have been subjected to peer review and have been cited by other researchers and the World Health Organization. I have published collaborative scientific articles in peer reviewed journals with colleagues from other main line or traditional universities and institutes from the disciplines of chemistry, toxicology, epidemiology and oc-

cupational medicine. These scientists work at Columbia University School of Public Health, SUNY Buffalo Medical Center, the University of Rochester Medical Center, the University of Amsterdam in Holland, and University of Helsinki in Finland, the University of Umea in Sweden, Health and Welfare Canada, Mt. Sinai Medical Center in New York City, Midwest Research Institute, ERGO Laboratories in Hamburg, Germany, the food analysis laboratory in Norwich, England of the British government, the food analysis laboratory of North Rhine Westphalia in Germany, the University of Nebraska, the Department of Public Health of Michigan and the Agent Orange Commission of Massachusetts, the Academy of Sciences of China, and the Academy of Sciences of the former Soviet Union, the Hanoi and Ho Chi Minh City (Saigon) medical schools, and Daiichi College of Pharmaceutical Sciences in Japan, concerning the Japanese PCB and dibenzofuran rice oil incident.

8.

I have served as peer reviewer, consultant, and invited attendee at meetings of the World Health Organization which concerned dioxins, dibenzofurans and PCBs on a number of occasions during the past 10 years. At these meetings, I have supplied my own original scientific data on human tissue levels of these chemicals for World Health Organization publications.

9.

I have recently served as peer review for the Agency for Toxic Diseases and Substance Registry of the Centers for Disease Control and Prevention of the US Public Health Service for their Toxicological Profile documents on (a) PCBs, (b) dibenzofurans, and (c) dioxins.

10.

I served as participating scientist to the U.S. Environmental Protection Agency ("EPA") for their "Human Health Assessment" document for the dibenzofurans and

th[ei]r "Bioavailability of Dioxins" document and prepared written and gave verbal reports to the EPA for its current review of human health assessment of dioxin. I presented my research findings and recommendations to the Agent Orange and dioxin review committee of the Institute of Medicine of the National Academy of Sciences, part of which was incorporated into their final report published in 1993.

11.

I have presented numerous papers at most of the recent International Dioxin Symposia during the past 10 years and also presented at the American Public Health Association national meetings, and other meetings including the American Association for the Advancement of Science. The subjects were dioxins, dibenzofurans and/or PCBs.

12.

I have performed original dioxin, dibenzofuran and PCB research in Vietnam for over 10 years, the former Soviet Union since 1988, and Japan for a number of years. I was the principal investigator for an Agent Orange and dioxin project for the Agent Orange Commission working with the Michigan Department of Public Health and also for the Massachusetts Agent Orange Commission[.] These were subsequently published in peer reviewed scientific journals.

13.

I serve, or have served, as reviewer for a number of scientific journals in the past few years. At present, I am co-chairman of the research committee of the Association of Teachers of Preventive Medicine, an association of medical school faculty members in preventive medicine. I also serve as a medical consultant for the American Legion and advise them on dioxin and Agent Orange issues.

14.

I currently serve, and have served for over 10 years, on my medical school's research committee. I served for two years as a National Institutes of Health Research Fellow in Anatomy at Harvard Medical School, and one year as a National Institutes of Health Clinical and research fellow and Instructor in Medicine at Massachusetts General Hospital of Harvard Medical School.

15.

I served two years in the US Army Medical Corps during the Vietnam war, and was honorably discharged as a major. I serve as scientific and medical consultant to the American Legion on matters of medicine, Agent Orange and dioxins.

16.

I served for between two and three years as director of the Broome County (New York) Health Department. During this period, the State of New York Building in Binghamton, New York, had a fire involving a transformer in its basement. The transformer contained PCB dielectric fluid. I saw first hand the public health consequences of such a fire and also learned first hand about the consequences of burning or heating of PCBs which include the creation of dibenzofurans and dioxins. As noted above, I have done extensive research into this area since that time. As an aside, the fire caused very little property damage but the contamination caused by the PCBs, PCDFs and PCDDs has kept the building unsafe and vacant for more than 10 years and over forty million dollars has been spent on cleanup efforts.

OPINION

17.

I have been asked to render an opinion as to the causal relationship between Robert Joiner's exposure to PCB

contaminated mineral oil dielectric fluids and the lung cancer from which he suffers. It is my opinion, to a reasonable degree of medical and scientific certainty, that Robert Joiner's exposure to PCB contaminated mineral oil dielectric fluid is the cause of his lung cancer. I believe that Robert Joiner's exposure to PCB contaminated mineral oil dielectric fluid served as a promotional effect on his lung cancer cells, probably initiated by cigarette exposure years before and caused him to contract lung cancer at the very young age of 37. But for Robert Joiner's exposure to PCB contaminated mineral oil dielectric fluid I believe he would not now be suffering from lung cancer.

METHODOLOGY

18.

In reaching the opinions set forth above I have followed the methodology usually and generally followed by physicians and scientists. This methodology included at least the following steps:

A. I interviewed Robert Joiner and discussed with him his general health, his medical history, his family medical history including but not limited to other victims of cancer, his exposure to other potential carcinogens including but not limited to tobacco, his work history, and his specific tasks at work with special interest in his work involving transformer repair.

B. I reviewed Robert Joiner's deposition testimony and a sworn statement he had provided to me.

C. I reviewed Robert Joiner's medical records before and after he was diagnosed with lung cancer. Included in this review was a review of the adipose tissue testing performed by Triangle Laboratories and a discussion with the chemist who performed the tests of the methodology he followed.

D. I reviewed a videotape which illustrated the conditions in which Robert Joiner worked while repairing transformers.

E. I reviewed the results of testing, (only tests performed after 1986 were available), for PCB on transformers owned by Robert Joiner's employer which were representative of the transformers on which Robert Joiner worked and to which he was exposed.

F. I reviewed the (toxicological and biochemical) scientific literature (clinical and epidemiological and wildlife) on animals, humans which has been published in the areas of PCBs, dibenzofurans, and dioxins, a sample of which is discussed below. Additionally, I have reviewed the scientific literature which was presented or discussed at scientific meetings I have attended in the past ten years, or that is with the documents in paragraphs 9 and 10 above.

G. I reviewed the deposition testimony of Plaintiffs' experts—Dr. Daniel Teitelbaum and Dr. Larry W. Robertson, Ph.D. as well as the deposition testimony of Defendants' experts—Dr. Phillip Cole, Dr. William Bailey, and Dr. William Waddell, Ph.D. I have aso reviewed the affidavit of Dr. Arthur Frank, another of Plaintiffs' experts.

H. I relied on my own personal training and experience in that I have devoted the last ten years of my life to the study of dioxins, dibenzofurans and PCBs and am uniquely qualified to opine as to health effects, including the promotional effects on initiated cancer cells, of these chemicals.

I. I eliminated other causes, to a reasonable degree of medical certainty.

J. I know that PCBs, dioxins and dibenzofurans and their metabolites tend to accumulate in lung tissue, as demonstrated in the scientific literature in a number of countries. The lungs are the organ most affected in Robert Joiner.

This methodology allowed me to understand the carcinogenic potential of the chemicals to which Robert Joiner

was exposed, and allowed me to understand and discover the mechanism which caused Robert Joiner's lung cancer.

EXPLANATION

19.

PCBs are synthetic or man-made chemicals, which are very persistent in the environment and in humans. They are toxic to humans and animals. PCBs did not exist until they were manufactured, primarily since 1929. PCBs are very similar chemicals to dioxins and dibenzofurans, which are also very toxic synthetic chemicals. They are frequently found together. They are all very persistent and highly toxic, although of the several hundred congeners of these chlorinated chemicals, there are some which are much more toxic than others; similarly, some are not as toxic or as persisent as others. The higher chlorinated PCBs typically used in dielectric fluids (Aroclors) were typically of the more toxic variety. We learned from Christopher Rappe and H.R. Buser, European chemists, that when PCBs burn in the presence of oxygen they form much of the more toxic dibenzofurans and some dioxins. When the chlorinated benzenes sometimes found in PCB transformer fluid burn, they yield higher amounts of dioxins and lesser amount of dibenzofurans. Dibenzofurans are usually found in PCB transformer fluids, as reported in numerous reports and at many scientific meetings. In the Binghamton, New York transformer fire, we found PCBs, dibenzofurans and dioxins in the soot and in the air after the fire. This mixture was and is regarded as highy toxic and dangerous to human health, by the New York State Department of Health, the U.S. EPA and the Broome County (NY) Health Department.

20.

Dioxins, PCBs and dibenzofurans have been shown to be toxic at extremely low levels in humans, in wildlife and in animal experiments. They cause cancers, adverse re-

productive effects including malformations, immune deficiency or the inability to fight cancers and infections, liver damage, nervous system damage, endocrine system damage and other health effects. They may be complete carcinogens, as they act in animals; but certainly are also at least potent promoters of cancer in animals and humans. This has repeatedly been reviewed by Huff at NIH and Lucier at NIH. Recent work at NIH shows no threshold for various biochemical endpoints tested by Lucier and colleagues. The rice oil poisoning incidents in Japan in 1968 and Taiwan in 1979 show that small amounts of PCBs and dibenzofurans can cause very serious health effects, including malformations, cancer death and learning disabilities. These health effects have been shown by Masuda and Kuratsune and colleagues in Japan. Consistent with this is the work of Walter Rogan of NIH who studied PCBs in North Carolina and the rice oil incident of Taiwan with Drs. Shu, Guo, Yu and others. Recent publication of dosing experiments of pregnant rats by Peterson and colleagues showed even the lowest dose employed produced brain and endocrine system damage to the offspring.

21.

Robert Joiner, by occupational history, was exposed at work, for a long period of time on a regular basis to PCBs and other transformer fluid contaminants routinely, after fires and high heat incidents, and when there was heating during the repair process. These exposures were above and beyond the exposures suffered by the general population. The exposure of the general population is now known to be higher than previously thought, so the total amount he was exposed to was greater than that from work alone. He, like all other Americans, was also exposed to many other chemicals including initiators of cancer. Therefore, the initiating and promoting effects of the amounts of the PCBs, dioxins and dibenzofurans was certainly enough to have contributed to his lung cancer, to the best

of my medical and scientific opinion. He breathed the chemicals, got them on his hands, absorbed some through the skin and ate food contaminated with some of these chemicals. These exposure mechanisms exposed Robert Joiner to PCB levels well above those experienced by the general population.

22.

I reviewed the methodology followed by Triangle Laboratories in its adipose tissue tests for dioxins and dibenzofurans. There are several problems with the analysis performed by Triangle Laboratories. I have published work concerning adipose tissue testing on several occasions, and am familiar with results from proper testing techniques. I discussed the techniques followed by Triangle Laboratories with the chemist who conducted the tests. I believe mistakes were made. I do not believe that a reasonable scientists could use these results to compare Robert Joiner to other humans. The results show no detectable levels of PCDDs in Robert Joiner's blood for congeners which are known to exist at detectable levels in adults in North America. This casts considerable doubt on the methodology followed and further convinces me that no reasonable and experienced dioxin medical scientists would rely on them.

In addition to problems with methodology, there is no control group to which Robert Joiner can be compared. In adipose tissue tests, the subject's results are compared to the general population (the "control") to determine how the subject compares. No study has been documented that examines subjects who have both experienced weight loss associated with cancer, chemotherapy associated with cancer, and radiation therapy associated with cancer, as well as been subjected to excessive PCB, dioxin or dibenzofuran exposure. As a result, there is no control group to which Robert Joiner can be compared. Accordingly, even assuming the results were analytically accurate, as a scientist I cannot rely on them for accurate exposure assessment.

This point was made in the 1993 Institute of Medicine-National Academy of Sciences Agent Orange Report.

Adipose levels which are low do not mean that higher levels did not exist at earlier times. This is because PCBs are metabolized and excreted from the body over time. The scientific literature bears this out. Perhaps the best documented group of non-occupationally exposed victims of PCBs are the survivors of the 1968 Yusho rice oil PCB and furan poisoning. Twenty-five years after unquestionably high exposures, many of these victims had PCB levels which had returned to those of the general population—or nearly so.

If the test results are valid, they prove that Robert Joiner's body is contaminated with PCBs. There is no normal level of PCBs in humans. Human beings should have absolutely zero PCBs in their systems.

23.

It should be remembered that the National Institute on Safety and Health (NIOSH), the official U.S. government worker research institute, in its late 1970's PCB Criteria Document, stated that there is no safe amount of PCBs. Since these chemicals have been shown to have non-threshold curves in recent biochemical studies at the National Institutes of Health, it seems reasonable to conclude that any additional amount of these chemicals can lead to increased risk of serious health damage.

24.

We know that the lung is the favorite site for finding metabolites of PCBs and related chemicals as well as the chemicals themselves. This has been shown by Nagayama, Masuda, Brandt and others. With a concentration of these carcinogenic compounds in the lung, it is reasonable to believe that, with long time occupational exposure without protection or with adequate protection, these chemicals

were related to the lung cancer which is killing Robert Joiner. We also know that these chemicals when given to animals, without other initiators of cancer, will, in a dose dependent fashion, cause cancer in rodents, a common test method used to indicate what may happen in humans. These include scientific research by Kociba, Norback, Kimborough, Anderson and many others. They also promote induction of the enzyme AHH in cell cultures, another test which paralles human toxicity for these and similar chemicals.

25.

In addition, we know that Bertazzi has found an excess of lung cancer in PCB workers in a peer reviewed published epidemiology study, *Cancer Mortality of Capacitor Manufacturing Workers*, Bertazzi et. al., American Journal of Industrial Medicine 11:165-176 (1987). Kuratune and other Japanese workers also reported an increase in lung cancer in male PCB and dibenzofuran rice oil exposed persons in Japan. (Ikeda, et. al., *A Cohort Study on Mortality of Yusho Patients—A Preliminary Report*, Fukuoka Acta med., 78:297-300 and other studies support this). Further, although I have not known about the Monsanto documents until called recently to my attention, these documents prepared by Dr. E. Mahboubi of The Eppley Center, and Frederick R. Johannsen, Ph.D. of Monsanto, suggest that Monsanto's PCB exposed workers also were developing higher rates of lung cancer than would otherwise be expected. We also have the recent Institute of Medicine of the National Academy of Sciences Agent Orange report of 1993 noting that the literature supports human cancer and human cancer mortality from dioxin and Agent Orange, and does not refute or is not complete enough to come to scientifically conclusive evidence concerning many health effects of dioxin and related chemicals (*Veterans and Agent Orange; Health Effects of Herbicide Used in Vietnam*, National Academy Press, 1993

Washington, DC). I believe this work too supports my opinions.

26.

It is known that risk of lung cancer for former cigarette smokers decreases to general population levels with time after cessation of smoking. The fact that, despite not smoking for years, Robert Joiner still developed lung cancer, speaks strongly for the cancer promoting influence of PCBs, dibenzofuran[s] and dioxins in Robert Joiner's case. Also, in summary, in my professional opinion, the weight of scientific evidence regarding health effects of the very similar PCBs, dioxins, and dibenzofurans, including wildlife, in vitro and in vivo toxicology, and human clinical case reports, clinical studies and epidemiology studies, together point to these chemicals as being carcinogenic in humans, probably by being both promoters and initiators.

/s/ Arnold Schecter
DR. ARNOLD SCHECTER, MD, MPH

Sworn to and subscribed before me this 28th day of January, 1994.

/s/ Sally Kirtland
Notary Public
My commission expires: 9/30/94

Curriculum Vitae

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Marital Status:

Married, three children

Fellow:

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Physicians
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Birth Date:

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Diplomate:

American Board of Preventive
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Academic Position:

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SUNY Health Science Center
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Johnson City, NY 13790

Education:

1974-1975 Columbia University School of Public Health, M.P.H., 1975

1958-1962 Howard University Medical School, Washington, D.C., M.D., 1962

1954-1957 The University of Chicago, Chicago, Illinois, B.A. (Liberal Arts) 1954, B.S. (Physiology-Neurophysiology) 1957

1951-1953 Shimer College of the University of Chicago, Mount Carroll, Illinois

Training:

1991 Mini-Residency in Occupational Medicine, University of Cincinnati College of Medicine, Part I

1982 Occupational Medicine Course, University of Illinois Medical School, Chicago, Illinois

1982 Occupational Medicine Course, Mt. Sinai Medical Center, New York, New York

1979 Occupational Medicine Course, University of Illinois Medical Center, Chicago, Illinois

1979 Environmental Medicine and Environmental Health Course, Postgraduate School, New York University Medical Center

1978 Occupational Medicine Course, Asbestos, Mt. Sinai Medical Center, New York, New York

1968 Course in Aviation Medicine, U.S. Army, Fort Rucker, Alabama

Professional Experience

1979-present Professor, with tenure, Department of Preventive Medicine, Clinical Campus at Binghamton, SUNY Health Science Center/Syracuse, College of Medicine, Binghamton, New York

1979-1981 Commissioner of Health, Broome County Health Department, Binghamton, New York also Medical Director, County Home Health Nursing Service, Acting Director of Willow Point Nursing Home, Binghamton, New York (part-time), Medical Director, Home Health Nursing Service

1975-1979 Clinical Associate Professor, Department of Preventive Medicine and Community Health, College of Medicine and Dentistry of New Jersey, New Jersey Medical School, Associate Director, Office of Primary Health Care Education, Office of the Dean, 1976-79

1972-1975 Assistant Professor, Dept. of Psychiatry, Director of Clinical Research in Drug Abuse; Coordinator and Faculty Member, Career Teacher Training Center in Drug and Alcohol Dependence Career Teacher Training Center and Division of Alcoholism and Drug Dependence, Drug and Alcohol Abuse Treatment Programs, State University of New York, Downstate Medical Center University of New York Health Science Center at Brooklyn and Kings County Addictive Disease Hospital, Brooklyn, New York

1971-1972 Director, Inpatient Rehabilitation Center, Drug and Alcohol Rehabilitation Program, Kentucky Region Eight Mental Health and Mental Retardation Board, Inc., Louisville, Kentucky

1969-1970 General Practitioner, West Point, Kentucky and Senior Aviation Medical Examiner (Federal Aviation Administration designee)

1967-1969 Captain, then Major, United States Army Medical Corps, Fort Knox, Kentucky

1966 Surgical Intern, Beth Israel Hospital, Boston, Massachusetts (January 1-December 31 Dr. Jacob Fine, Chairman)

1964-1965 Instructor, Department of Medicine, Renal Unit and National Institute of Health sponsored Clinical and Research Fellow; Harvard Medical School of the Massachusetts General Hospital, Boston, Massachusetts (Dr. Alexander Leaf, Director)

1962-1964 Postdoctoral Research Fellow, Harvard Medical School, Boston Massachusetts, 1962-64, funded by National Institute of Health, Department of Anatomy (Renal Ultrastructure, Dr. Don Wayne Fawcett, chairman)

Recent National and International Scientific Panels and Awards

Advisor to the Government Accountability Project, 1993

American College of Preventive Medicine's representative to the Physician Consortium on Substance Abuse Education, U.S. Public Health Service, 1992-present

Advisor to the Natural Resources Council of Maine, 1992

Technical Review Panel of the Great Lakes Protection Fund, 1990-present

Advisor to the National Veterans Legal Services Project, 1990-present

Invited member of the "U.S. Baikal (Russia) Research Association," 1991-present

Advisor to The American Legion's Science Panel, 1991-present

National External Science Advisory Panel of the Michigan Agent Orange Commission, 1989-present

Advisor to the National Veterans Legal Services Project, 1989-91

Advisor to the Environmental Defense Fund, 1984-89

Awarded the "Pacesetter Award" from the Commonwealth of Massachusetts for dioxin research, 1987

Temporary consultant to the World Health Organization of the United Nations on Chlorinated Dioxins and Related Chemicals in Human Breast Milk. Meetings at: Oslo, Norway, October 1986; Copenhagen, Denmark, November 1986 and February 1988; Toronto, Canada, September 1989; Rovaniemi, Finland, June 1990; Bayreuth, Germany, September 1990

Peer Review Committee (Expert Panel), USEPA *Biological Health Assessment Document, Polichlorinated Dibenzofurans,* 1986

Peer Review, USEPA, *Chlorinated Dioxins and Furans in the General U.S. Population: NHATS FY87 Results,* 1991

Contributor to "Bioavailability of Dioxins," *U.S. Environmental Protection Agency 1984 Workshop Proceedings,* Government Printing Office, 1985

Planning Committee, International Symposium on Dioxins and Related Chemicals, 1984, 1985

Recent National and International Scientific Presentations

Institute of Medicine, National Academy of Sciences, Scientific Workshop on Exposure Assessment, 1992

National Institute of Environmental Health Sciences and Health and Welfare Canada, Breast Cancer Prevention: Opportunities for Research, 1992

New York Chapter, Vietnam Veterans of America, 1992

Michigan Agent Orange Commission Meetings, 1991-1993

American Chemical Society National Meetings, 1983-1991

International Symposium on Dioxins and Related Chemicals, 1984-1992

American Public Health Association Annual Meetings, 1985-1991

American College of Preventive Medicine, Annual "Prevention" meetings, 1985-1991

American Association for the Advancement of Science, 1987

Prevention '86, Coordinator: Chemicals in the Environment: What Can Be Done?, Dioxins and Related Chemicals as a Model, 1986

Banbury Conference, invited speaker, Cold Spring Harbor, NY, 1983 and 1990

Gordon Conference on toxicology of dioxins, 1983 and 1985

Wisconsin Vietnam Veterans of America National Meeting, 1989

Academic/Professional Memberships

Association of Teachers of Preventive Medicine

Association of Teachers of Preventive Medicine Research Committee

American College of Epidemiology

American College of Occupational and Environmental Medicine (Fellow)

American College of Preventive Medicine (Fellow)

American College of Physicians (Fellow)

American College of Preventive Medicine Physician Consortium on Substance Abuse Education

Association of American Medical Colleges (1976-1990)

American Association for the Advancement of Science

American Public Health Association

American Society for Cell Biology (1962-1990)

Broome County Medical Society

New York Academy of Sciences

New York State Medical Society

New York State Occupational Medicine Association

Massachusetts General Hospital Housestaff Alumni Association

Microscopy Society of America

Society for Epidemiologic Research

Society for Occupational and Environmental Health

University Committees

Executive Committee, Clinical Campus, 1992-present

Grades Committee, 1992-present

Research Committee, 1979-present

Student Appraisal and Promotions Committee, 1979-1980

Search Committee, Department of Preventive Medicine, 1980-1983

Educational Policy Committee, 1979-1981, 1992-1993

Coordinators' Committee, 1979-1983

Library Committee, 1982-1987

Television Health Features Advisory Council, SUNY Binghamton, 1980-1981

Community Service

Broome County Nursing Home Advisory Board, *ad hoc*, 1979-1984

Broome County Mental Health Advisory Board, 1979-1984

Broome County Mental Health Advisory Board Subcommittee and Drug Abuse and Alcohol Abuse, 1983-1984

Broome County Health Department: Home Health Advisory Committee *ad hoc*

Broome County Health Department: Medical Advisory Committee *ad hoc*

Broome County Health Department: Advisory Board of Health *ad hoc*

Broome County Medical Society: Board of Directors, 1979-1984

Broome County Medical Society: Public Health Committee, 1979-1982

Broome County Water Resources Commission, *ad hoc* appointee

New York-Pennsylvania Health System Agency, Community Board

New York-Pennsylvania Health System Agency Planning Committee

Our Lady of Lourdes Hospital Hospice Advisory Board

Our Lady of Lourdes Hospital Hospice Finance Committee

Central New York Affiliate of the New York State Public Health Association

Planned Parenthood of Broome and Chenango Counties, Inc., Medical Advisory Committee

Broome County Chamber of Commerce

Broome County Chamber of Commerce Professional Committee

State Univerity of New York, Binghamton, Speakers' Bureau

Twin Tiers Home Health Nursing Service Board of Directors

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Editorial Activities

Cofounder and Associate Editor, *The American Journal of Drug and Alcohol Abuse*. New York, New York: Marcel Dekker, Inc., 1973-1978

Editorial Board, *The American Journal of Drug and Alcohol Abuse*. New York, New York: Marcel Dekker, Inc., 1978-present

Editorial Advisory Board, *Substance and Alcohol Actions/ Misuse*. Elmsford, New York: Pergamon Press, Inc., 1979-present

Reviewer, *Journal of Occupational Medicine*

Reviewer, *Journal of the American Public Health Association*

Reviewer, *Environmental Science & Technology*

Reviewer, *Academic Medicine*

Books

Schecter, A. (ed.). *Rehabilitation Aspects of Drug Dependence*. Cleveland, Ohio: CRC Press, 1977.

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Schecter, A. (ed.). *Biomedical Issues in Drug Abuse*. Volume I, Proceedings 1978 National Drug Abuse Conference. New York, New York: Plenum Publishing Co., 1981.

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Schecter, A. (ed.) *Dioxins and Health*, Plenum Press, in preparation for 1993 publication.

Articles

1. Schecter, A.J. and D.W. Fawcett. (Abstract) "Intracellular microtubules in mammalian podocytes," *Anat. Record*, 148:2, 332, 1964.
2. Schecter, A. J. (Abstract) "Fine structure studies of the urinary bladder of bufo marinus," *Anat. Record*, 151:3, 412, 1965.

3. Schantz, A. and A. J. Schecter. (Abstract) "Iron hematoxylin and safranin O staining of epon embedded sections," *Anat. Record*, 151:3, 454, 1965.

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

AFFIDAVIT OF ARTHUR L. FRANK, MD, Ph.D.

Personally appeared before me, the undersigned officer duly authorized to administer oaths, Arthur L. Frank, MD, Ph.D., who after being duly sworn, deposes as follows:

1.

My name is Arthur L. Frank, MD, Ph.D. I have reached my majority and am mentally competent. I have personal knowledge of the facts set forth in this affidavit.

2.

I reside at 3320 Gondola Court, Lexington, Kentucky, 40513. My professional address is University of Kentucky, Department of Preventive Medicine and Environmental Health, Chandler Medical Center, Lexington, Kentucky, 40536-0084.

3.

I am a Professor and Chairman of the Department of Preventive Medicine and Environmental Health at the University of Kentucky College of Medicine. I am also the Director of the Occupational Medicine Program and Director of Graduate Studies, Master of Science in Public Health Degree Program.

I am a specialist in the field of occupational medicine, toxicology and preventive medicine. I obtained my medical degree from the Mount Sinai School of Medicine of the City of New York in 1972 and my Ph.D. from the City University of New York, Biomedical Sciences Pro-

gram at the Mount Sinai Medical Center in 1977. A true and current copy of my curriculum vitae is attached to this affidavit as Exhibit "A". It accurately reflects my training and experience. Exhibit "B" to this affidavit accurately reflects my publications and presentations in the field relevant to the opinions given in this affidavit.

4.

I have written numerous peer reviewed papers, and have written papers reviewing the works of others, in the field of the epdimology and etiology of lung cancer. I have been interested in the subject of occupational lung cancer for much of my academic career and have researched this field extensively. My papers concerning occupational lung cancer, and the epidemiology and etiology of lung cancer, have been supported, in many cases, by original research that I conducted and directed. I have been qualified as an expert witness to assist juries in understanding the causes of lung cancer on numerous occasions, and in numerous courts, throughout the United States.

5.

Lung cancer, like other cancers, begins with an initiated cell. The initiator can be any number of things including, but not limited to, tobacco smoke. An initiated cell does no harm by itself until it is promoted. An initiated cell can survive for a number of years without any harmful effects on the body. There are a wide variety of known and suspected promoters of lung cancer.

6.

Epidemiology studies and statistics, and my own personal observations and experience, indicate that lung cancer is extremely rare for a thirty seven year old white male in the United States. This is true even for persons with a history of tobacco use. Lung cancer, as a general rule, is not seen until much later in life.

7.

Based on available studies, and my person observations and experience, it is my opinion, to a reasonable degree of medical certainty, that lung cancer in a thirty-seven (37) year old white male, even with a history of cigarette smoking, would be as a result of exposure to other exogenous factors which lead to the rapid development of the malignancy. The exogenous factors are often referred to as promoters and are what make, or promote, an essentially harmless initiated cell into a harmful malignant cancer.

8.

I am familiar through my training and experience and research, with the types of cancer which attack the lung. I have reviewed the medical records of Robert Joiner with respect to his lung cancer and have reviewed his use of tobacco and exposure to tobacco smoke. The cell type of cancer that Mr. Joiner has, the type known as "small cell" carcinoma of the lung, has multiple recognized causes, including, but not limited to, tobacco smoke and such occupational exposures as ionizing radiation and exposure to bischloromethyl ether. Other occupational carcinogens, likewise have been associated with the development of this type of carcinoma. No cancer is exclusively one type of cell. No one cell type is exclusively related to cigarette smoke or any other single causative agent. In other words, the fact that Mr. Joiner has a small cell type of lung cancer does not, in and of itself, provide any definitive link to tobacco smoke being the cause of that cancer. It is more likely than not, given Mr. Joiner's limited tobacco use, and also considering his second hand tobacco smoke exposure, and given his age at the onset of lung cancer, 37 years, that tobacco smoke served only as the initiator of the cancer and that some other agent served as the promotor of the initiated cells. It was the promotion of the initiated cells which caused Mr. Joiner to be harmed.

By: /s/ Arthur L. Frank, MD
ARTHUR L. FRANK, MD, Ph.D.

Subscribed and sworn before me on this 28th day of January, 1994.

/s/ Rebecca L. Payne
Notary Public
My commission expires: 1-13-98

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

AFFIDAVIT OF DANIEL T. TEITELBAUM, M.D.

Daniel T. Teitelbaum, M.D., being duly sworn, deposes and says:

1. My name is Daniel T. Teitelbaum, M.D.; I have personal knowledge of every statement made in this Affidavit.

I am a practicing medical toxicologist in Denver, Colorado. I am adjunct professor of Environmental Science and Engineering Ecology at the Colorado School of Mines, where I teach the graduate toxicology courses in occupational and environmental toxicology. I am also associate clinical professor of medicine and preventive medicine at the University of Colorado Health Sciences Center, where I teach toxicology and the epidemiology of toxic diseases. In addition, I am visiting professor of medicine and toxicology at the faculty of medicine of Technion, the Israel Institute of Science, in Haifa, Israel. I am a founder and former director of Rocky Mountain Poison Control Center, and of the Physicians Poison Consultation Service at the University of Colorado Medical Center. I have been chairman of the Diagnostic Product Advisory Committee and the Toxicology Diagnostic Product Advisory Committee of the United States Food and Drug Administration. I have been a member of several committees and consultation panels of the United States Environmental Protection Agency. I was a member of a Blue Ribbon Panel of the Executive Office of the Presi-

dent which was called together to advise on future direction of research for the Environmental Protection Agency and the National Institutes of Environmental Health Sciences. I have been a special consultant for the United States Occupational Safety and Health Administration on many occasions. I assisted in the development of standards for workplace exposure to benzene, formaldehyde, ethylene dibromide and other materials. I participated in the development of the medical surveillance protocols for workers exposed to lead, formaldehyde and benzene, and I testified at the OSHA public hearings dealing with these Standards.

In the recent past, I have taught two courses at the Federal Judicial Center under the auspices of George Washington University for the Federal Judiciary on issues of toxicology and the epidemiology of toxic diseases.

I have written more than forty articles which are published in peer reviewed journals. I have also presented many lectures and talks in the area of toxicology and the diagnosis and management of toxic disease.

I have been an advisor and panel member of several World Health Organization working parties on toxic disease, including a new panel on genetic susceptibility to toxic substances.

I received my M.D. degree in 1964 from the Albert Einstein College of Medicine and I completed an internship at Montefiore Hospital in New York City. I was a resident in internal medicine and a fellow in toxicology at the University of Colorado Health Sciences Center. I completed my formal training in 1968.

I was a founder of the American Academy of Clinical Toxicology and the American Board of Medical Toxicology. I was first chairman of the examining board of the American Board of Medical Toxicology. I was certified by the American Board of Toxicology in 1975 and recertified by examination in 1976.

I am currently involved in the day to day practice of medical toxicology and in consultation in the area of medical toxicology, for medical legal purposes, for corporate clients, for labor, for government agencies, regulatory agencies, police agencies and for civil litigation. In the course of my work I have interviewed, examined and treated numerous patients who were employed in the electrical trades. These tradesmen and craftsmen included licensed electricians, electronic technicians and technologists, engineers, linemen, and powerhouse employees. In addition, I have interviewed and examined transformer repairmen for utility companies, private manufacturers, govenment agencies, and railroad and other transportation companies. I have visited powerhouses, transmission substations, field transmission sites, electrical and electronic manufacturing and assembly plants and other facilities in which the technical and craft persons whom I interviewed and examined were employed.

As a result of this work, I have extensive knowledge of the handling of toxic substances, hazardous materials, electrical power, and other risks of a physical and chemical nature which are common to the electrical crafts and trades.

A copy of my curriculum vitae is attached as Exhibit 1.

2. During my evaluation of the matter of Joiner v. Westinghouse, et al., I carried out a comprehensive and traditional occupational medical assessment of Mr. Joiner in the offices of Northside Internists and Endocrinologists in Atlanta, Georgia. As part of this assessment I interviewed and examined him in Atlanta, Georgia on July 14, 1993, for several hours. In addition, I reviewed his past medical records, the data which was available about his workplace and materials with which he worked, depositions of Mr. Joiner, and others, and depositions of family members and co-workers about the nature of his work.

I also considered many other documents relevant to the questions which I was asked concerning Mr. Joiner's illness and its relationship to his occupational exposures to toxic substances.

In the course of my toxicologic evaluation of Mr. Joiner I utilized traditional medical assessment techniques. I also relied upon my extensive experience with workers in the electrical trades and my knowledge of the toxicology of the materials with which Mr. Joiner worked. I considered the fundamental mechanisms of toxicology and carcinogenesis as a manifestation of toxic outcome, the biology of cancer including the biology of small cell lung cancer, and the state of the art regarding the testing and evaluation of toxic substances for carcinogenic risk in humans. Attached to this affidavit as Exhibit 2 is a list of documents which I have reviewed in connection with this case. These documents have previously been furnished to defendants in the course of my deposition which was taken in Jacksonville, Florida on October 12, 1993.

MR. JOINER'S MEDICAL HISTORY

1. In the course of my evaluation of Mr. Joiner's current clinical condition and in order to understand the genesis of his lung cancer within the context of contemporary thought on carcinogenesis, I took an extensive medical history from Mr. Joiner. This medical history was provided to the defendants as an exhibit to my deposition (Dr. Teitelbaum's Deposition, Exhibit 10.) His medical history revealed there were a number of risk factors for lung cancer present in Mr. Joiner. These factors were, first, a family history of lung cancer in his mother, who died at age 64 and was a smoker. There is a less clear history of cancer in other relatives, which I could not further classify. A second risk factor was the fact his father had worked at a sand and gravel

mining company until the patient was approximately 7 or 8 years old. There is no evidence that Mr. Joiner has silicosis or any scarring as a result of household contact with silica which his father might have brought home on his clothing. However, current thought suggests that silica is a lung carcinogen in humans. It is possible but not at all probable that domestic exposure to silica may have contributed to Mr. Robert Joiner's overall lung cancer risk. Third, Mr. Joiner was a cigarette smoker from age 19 to age 27. According to the history which he gave to me and the statement in his deposition, he smoked 1 package of cigarettes per 24 hours for eight years, which yields an 8 pack year dose. He stopped smoking completely at age 27. Mr. Joiner avoided all cigarette smoke after the fourth Friday of April, 1982. Fourth, in 1973 Mr. Joiner began to work for the Thomasville Electric Utility, as a transformer repairman. He worked on oil filled transformers, many of which were contaminated with polychlorinated biphenyl.

According to the extensive occupational history which I took from Mr. Joiner and according to the documents provided to me, his deposition, and my knowledge of the usual practice of electrical transformer repairmen in the era in question, it is clear that Mr. Joiner worked with PCB contaminated mineral oil, mineral oil per se, mineral spirits as a cleaning agent, and paints. He was repeatedly exposed to the inhalation of smoke and fume from the process of "baking out transformers" utilizing stadium lights as a heat source. His work practices clearly indicated to me that in accord with well established principles of pharmacokinetics he would have been substantially exposed to polychlorinated biphenyls and polychlorinated dibenzofurans in mineral oil, mineral oil per se, and mineral spirits, by skin, respiratory and oral route and to fumes, smoke, dust and aerosol from "baking out of transformers" during the course of his work. I did not

find any other risk factors for lung cancer or any other significant exposures in his occupational history.

MR. JOINER'S CIGARETTE SMOKING AND IT'S RELATIONSHIP TO THE CAUSATION OF HIS LUNG CANCER

1. In the defendants' motion for summary judgement, defendants' attorneys propose that "even as Mr. Joiner's own experts acknowledge he has had consistent, substantial exposure to cigarette smoke for many years." This statement could not be farther from the truth. The defendants' attorneys cite my deposition at pages 48, 54, 55 and 56, both out of context and incorrectly. On page 48, lines 1-11, I stated as follows, "Mr. Joiner smoked for a relatively significant period of his life, but from the point of view of causation of lung cancer, a very—a low-end dose and early, and he stopped 12 years approximately before he got sick. But if the most recent studies on smoking and cancer are correct, previous assumptions that as time passed the risk would disappear have been unduly optimistic. So we have some risk of lung cancer because he was a smoker; however, the likelihood of his developing lung cancer at age 37 on a statistical basis is extremely small." I then continued, lines 12-17, "If you compared the lung cancer rates at age 60, which are around 400 per 100,000 person years, with lung cancer rates in the 30's, which are almost too low to detect, somewhere around 10 to 15 per 100,000 and most of those in the later 30's rather than the early 30's, it's pretty—pretty low risk, but it's there." By no stretch of the imagination can this comment be interpreted to mean what defendants have suggested I said on page 9 of their motion for summary judgement. Consideration of the further references on pages 54, 55 & 56 of my deposition will confirm that at no point did I concede or would I have agreed that Mr. Joiner had "consistent, substantial exposure to cigarette smoke for many years." Mr. Joiner's

smoking history has been related above. It is contained in the medical history which I took and is restated in his deposition. While there may be some discrepant smoking history in his medical record, that history was not given under oath. His history under oath in his deposition and my medical history are concordant.

2. A remote smoking history of 8 pack years can only be considered a minimal risk factor for the causation of lung cancer. Such a history cannot be associated with any particular cell type of lung cancer. So few lung cancers at this age have been collected in the literature that no statistically meaningful analysis of histological type at age 37 is possible. On the basis of the data which is available, it is clearly extraordinary for lung cancer to develop in a 37 year old male with a brief smoking history which terminated eleven years prior to the onset of his cancer. The age and risk factor considerations strongly point to the operation of other carcinogens and cocarcinogens in Mr. Joiner's cancer, since cigarette smoking is so unlikely to be a sufficient cause of lung cancer at his age.

3. In their motion for summary judgment, defendants' attorneys suggest that some special relationship exists between small cell cancer of the lung and cigarette smoking. They do not cite any particular authority for this position. Based upon my knowledge and understanding of the literature dealing with lung cancer and cigarette smoking it is apparent that they are quoting a paper by Stayner and Wegman[1] which was published in 1983. The report suggested that, "cigarette smoking was significantly associated with all three histological types of lung cancer, with the strongest relationship being for

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[1] Stayner LT; Wegman DH
Smoking, occupation and histopathology of lung cancer: a case-control study with the use of the Third National cancer survey. JNCI 1982; 70:421-6

small cell carcinoma."[2] Further study since 1983 has clearly established that the relationship between cigarette smoking and lung cancer is very strong, and that the most likely type of cancer to develop is squamous cell carcinoma, not small cell cancer. This likelihood that squamous cell cancer will develop in white male smokers is present at virtually all ages. Small cell cancer represents only 14 to 15 percent of all cancers in cigarette smokers who are white males at all ages.[3] Stockwell, et al., in a very large study of 35,000 smoking lung cancer deaths in Florida reported that "Among males, adenocarcinomas represent the most frequent cell type only among younger, never-smoking males. In other categories squamous carcinomas dominate."[3]

4. The Stockwell study and other studies have confirmed that the current state of the art is as described by Hegmann, et al., 1993, that "There was no predisposition toward a specific histologic type of lung cancer" in cigarette smokers.[3] The mass of literature on smoking and lung cancer makes it clear that there is no particular predisposition to any given histologic type of cancer among smokers. It also makes it manifest that the occurrence of lung cancer in a smoker whose dose of cigarettes is as low as Mr. Joiner's and who is as young as Mr. Joiner, is very unusual.

5. Small cell lung cancer has been reported in radiation exposed individuals,[4] in radon exposed individu-

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[2] Stockwell HG; Armstrong AW; Leaverton PE
Histopathology of lung cancers among smokers and nonsmokers in Florida.
Int J Epidemiol 1990; 19 Suppl 1:S48-52

[3] Hegmann KT; Fraser AM; Keaney RP; Moser SE; Nilasena DS; Sedlars M; Higham-Gren L; Lyon JL
The effect of age at smoking initiation on lung cancer risk.
Epidemiology 1993 Sep;4(5):444-8

[4] Land CE; Shimosato Y; Saccomanno G; Tokuoka S; Auerbach O; Tateishi R; Greenberg SD; Nambu S; Carter D; Akiba S; et al

als,[5] in persons exposed to chloromethyl ethers,[6] and in other toxic exposures[7] which have resulted in lung cancer. In my opinion, the extraordinary occurrence of lung cancer, at a young age and with minimal cigarette smoking in a person whose latency period is brief, and whose family history of cigarette smoking and lung cancer does not provide an adequate explanation for the occurrence of this disease, demands further analysis. I have carried out such an analysis, in accord with accepted toxicologic practice, and I have concluded the principal additional risk factors which are present and which have determined the causation of lung cancer in Mr. Joiner in a multifactorial fashion were: 1. work with PCB contaminated mineral oils, mineral spirits, and mineral oil per se; 2. his family history, and; 3. his smoking history. Together these factors have combined to result in lung cancer at a very young age in a minimal smoker. I believe that the scientific literature strongly supports this position.

Radiation-associated lung cancer: a comparison of the histology of lung cancers in uranium miners and survivors of the atomic bombings of Hiroshima and Nagasaki.
Radiat Res 1993 May;134(2):284-43

[5] Biberman R; Lusky A; Schlesinger T; Margaloit M; Neeman E; Modan B
Increased risk for small cell lung cancer following residential exposure to low-dose radon: a pilot study.
Arch Environ Health 1993 Jul-Aug;48(4):209-12

[6] Figueroa WG; Raszkowski R; Weiss W
Lung cancer in chloromethyl methyl ether workers.
N Engl J Med 1973 May 24;288(21):1096-7

[7] Ishikawa Y; Mori T; Kato Y; Tsuchiya E; Machinami R; Sugano H; Kitagawa T
Lung cancers associated with thorotrast exposure: high incidence of small-cell carcinoma and implications for estimation of radon risk.
Int J Cancer 1992 Oct 21:52(4):570-4

MR. JOINER'S WORK WITH PCB CONTAINING OIL AND HIS EXPOSURE TO PCBs

1. The defendants' attorneys in their motion for summary judgement have called into question my assessment of the extent and significance of Mr. Joiner's exposure to polychlorinated biphenyls in the mineral oil of the transformers with which he worked. They concede that at least 20 percent of the transformers handled at the Thomasville utility facility were contaminated with polychlorinated biphenyls manufactured by their clients. However, they argue that this exposure could not have produced a dose which was sufficient to cause Mr. Joiner's cancer. They incorrectly allege that I did not adequately consider the information available concerning the PCB contamination of the mineral oils in the transformers which Mr. Joiner handled.

2. During the course of my deposition I indicated that I had relied upon certain documents furnished by plaintiff's attorneys concerning the level of PCB contamination in various transformers. These documents included specific incident reports, during which Mr. Joiner was directly involved in the salvage of PCB containing transformers which had been involved in a lightning strike. The transformers were contaminated with PCBs up to levels of several hundred parts per million (Dr. Teitelbaum's deposition, Exhibit 16-B). In addition, a lightning strike and overheating of a transformer in the presence of oxygen in the dielectric fluid, inevitably produces polychlorinated dibenzofurans. PCDFs are carcinogens which are generally believed to contaminate all transformers at varying concentrations when PCBs, oxygen, and electric current combine. Such situations occur during arcing and transformer fires. Thus, Mr. Joiner would also have been exposed to polychlorinated dibenzofurans.

At the time of my deposition, I had not been furnished with specific transformer data concerning PCB content

which was then being analyzed by the plaintiff's attorneys. Since that time, I have received a database printout of analyses of transformer PCB content based upon documents furnished to the plaintiffs by the defendants. These documents indicated that 50.8 percent of the transformers handled by the Thomasville utility contained PCB's in concentrations greater than zero. Twenty-one percent of the transformers demonstrated PCB contents of 0 to 50 parts per million, 25 percent demonstrated concentrations of 50 to 500 parts per million, 4 percent contained greater than 500 parts PCB per million. Thus, 29.3 percent of all of the transformer fluids analyzed contained polychlorinated biphenyls at greater than 50 parts per million, and 21.5% had levels greater than zero but less than 50 ppm. Since transformers may contain between eight and five hundred gallons of transformer oil, the potential and actual exposure to Mr. Joiner would be enormous. (Personal Communication, Public Service Co., Colorado, 1994) [8] In my opinion, this is significant contamination and is consistent with what has been described in the scientific literature. It represents a substantial source of exposure to polychlorinated biphenyls for Mr. Joiner and his co-workers.

3. How polychlorinated biphenyls which are present in transformer fiuid are absorbed into the human body to deliver a dose of toxic substance to the target organs of the worker has been well defined. In Mr. Joiner's case it is clear that at least 2 significant routes and one minor route of exposure were present. The first of these routes was inhalation of mist and fume. The second was dermal exposure, and the third minor route was oral exposure.

Mr. Joiner reported that he constantly inhaled oil fumes. A standard working practice at the Thomasville utility included the use of stadium lamps to dry the cores of

[8] Personal communication, Public Service Company of Colorado, Jan. 1994

transformers being repaired in order to rehabilitate them. This drying process, which had to be carried out at a temperature above 180 degrees F. in order to achieve significant evaporation of the oil put a substantial amount of contaminated fume in the air. This resulted in eye, airway and chest irritation in Mr. Joiner. It delivered directly to the target organ, Mr. Joiner's lung, a significant dose of mineral oil, polychlorinated biphenyls, furans, mineral spirit and other contaminants.

The practice of heating PCB containing transformer parts to dry them out is not new. The disingenuous implication in the memorandum of the defendants' attorneys in their motion for summary judgment that there is something odd, peculiar or non-standard about this practice of heating transformer cores and interior parts in order to achieve oil drying, is surprising. In Hubert's text, entitled "Preventive Maintenance of Electrical Equipment," second edition, published by McGraw-Hill Book Company in 1969, there is a description of the process of heating mineral oil and Askarel® containing transformers in order to achieve drying. A specific warning appears on Page 73 as follows, "Warning. Every effort should be made to avoid getting liquid Askarel® or concentrated vapors from hot Askarel® on the skin. It is very irritating, especially to the eyes, nose and lips. Continued exposure to Askarel® may cause skin eruptions because of the absorption of the liquid through the pores of the skin. The recommended treatment for such irritations is castor oil for the eyes, and castor oil or cold cream for the nose, lips and other areas of skin."[9] Clearly it was well known by industrial engineers as long ago as 1969, that heating of PCB containing mineral oils in transformers could lead to chloracne and was a cause of substantial absorption of PCBs. Other studies have confirmed that this is so.

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[9] Hubert CI
Preventive Maintenance of Electrical Equipment.
2nd edition. New York: McGraw-Hill, 1969.

4. In an artfully crafted question which appears on page 58, lines 6,7 and 8 of my deposition, defendants' attorneys asked me, "Do you know what the skin absorption rate through the skin is of PCBs that are contained in contaminated mineral oil?" In response to that question, I indicated that I could not find any specific data on the question of rate of absorption. Studies had been done prior to the time of my deposition which address the issue of absorption in animal skin. There were no specific studies which dealt with living human skin. In 1990, Wester et al.,[10] published a paper entitled, "Percutaneous absorption and skin decontamination of PCBs: in vitro studies with human skin and in vivo studies in the rhesus monkey" in the Journal of Toxicology and Environmental Health; the investigators demonstrated that PCBs are efficiently absorbed through the skin, and that excretion from the body is slow. The vehicle within which the PCBs which were contained, water, trichlorobenzene, or mineral oil did not affect percutaneous absorption. In vitro skin absorption in human cadaver skin did not correlate with in vivo findings. This was due to the lack of PCB partitioning from the skin into the water receptor fluid, even with the addition of 6 percent Oleth 20® solubilizer. Since 1990, the same group of investigators has published more on the skin absorption of PCB. Wester, et al., in another paper in the Journal of Toxicology and Environmental Health, 1993, entitled, "Percutaneous absorption of PCBs from soil: In vivo rhesus monkey, in vitro human skin, and binding to powdered human stratum corneum" demonstrated that, "With in vitro percutaneous absorption through human skin, most of the Aroclor 1242 and Aroclor 1254 resided in the skin and the amounts

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[10] Wester RC; Maibach HI; Bucks DA; McMaster J; Mobayen M; Sarason R; Moore A
Percutaneous absorption and skin decontamination of PCBs: in vitro studies with human skin and in vivo studies in the rhesus monkey.
J Toxicol Environ Health 1990 Dec;31(4):235-46

were dependent upon dosing vehicle (water > mineral oil > soil)." [11] They further indicated that in the rhesus monkey, the percutaneous absorption of Aroclor 1242 was 13.8, plus or minus 2.7 percent of the dose. The absorption of Aroclor 1254 was 14.1, plus or minus 1 percent of the dose. These absorption amounts were similar to the absorption of Aroclor 1242 and 1254 from other vehicles such as mineral oil, trichlorobenzene, acetone. According to Wester's work, it is likely that humans absorb significant percentages of an administered dose of PCBs from a mineral oil vehicle, such as that to which Mr. Joiner was exposed. That the specific study has not been done in living human beings is hardly surprising. The general awareness of the extreme toxicity of the PCBs and their co-riders in the mineral oil would make it impossible to carry out an absorption study under the terms of current human investigational protocols.

5. Dermal absorption as a major route of body entry for PCBs has been addressed effectively in the medical literature. In a paper published in the American Industrial Hygiene Association Journal, 1987, Peter S.J. Lees and colleagues reported, "Evidence is presented to support the hypothesis that the dermal and dermal/oral routes of worker PCB exposure are the major contributors to total PCB body burden in the group of transformer maintenance and repair personnel studied." [12] Their calculations demonstrate that Mr. Joiner was significantly exposed to PCBs in mineral oil.

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[11] Wester RC; Maibach HI; Sedik L; Melendres J; Wade M
Percutaneous absorption of PCBs from soil: in vivo rhesus monkey, in vitro human skin, and binding to powdered human stratum corneum.
J Toxicol Environ Health 1993 Jul;39(3):375-82

[12] Lees PS; Corn M; Breysse PN
Evidence for dermal absorption as the major route of body entry during exposure of transformer maintenance and repairmen to PCBs.
Am Ind Hyg Assoc J 1987 Mar;48(3):257-64

This paper also confirmed that while the respiratory route could be a meaningful source of exposure to PCBs, "dermal contact and absorption of PCBs is the most significant source of exposure and the resultant body burden." [13] It is clear that Mr. Joiner, handled transformer oil without protective gear on many days during the course of his employment at the Thomasville utility facility, repeatedly entered into large transformers, transferred large quantities of transformer oil, handled the oil, kept his tools oiled with the oil, and had extensive dermal oil contact. In addition, Mr. Joiner had substantial respiratory exposure to oils, PCB and PCDF, because of the deliberate heating of transformer cores in order to dry them. His exposure was intensified by exposure to the heated transformer oil which was present as a result of arcing, lightning strikes, fires and other inevitable mishaps in the operation of transformers in the field. Together, these resulted in a significant, repeated acute and chronic exposure to polychlorinated biphenyls, polychlorinated dibenzofurans, mineral oil, mineral spirits and other contaminants within that mineral oil. I believe that it is more probable than not that Mr. Joiner underwent a significant, substantial, meaningful, toxic, and carcinogenic exposure to these materials between 1973 when he began to work at Thomasville and the time that his cancer occurred.

ROLE OF ANIMAL STUDIES IN PREDICTING HUMAN CARCINOGENICITY

1. Defendants' attorneys have suggested that animal studies are unreliable as a basis of opinions as to causation of cancer in humans. In my opinion, defendants have selectively read the literature. They continue to discount the enormous contributions made to the prediction of human cancer risk by carefully done animal studies. In a 1993 review of chronic life span toxicology studies, Monro commented as follows, "For such compounds, a study in rats at pharmacodynamically relevant dose levels

for 12-18 months will, in general, provide adequate information for carcinogenic risk assessment in humans." [13] Others, including Huff, in his most recent paper in The Journal of Pharmacology and Toxicology, entitled, "Issues and controversies surrounding qualitative strategies for identifying and forecasting cancer causing agents in the human environment" commented that, "Long term laboratory animals bioassays, despite the criticism leveled at them, were considered to be the most useful and valid techniques for identifying potential human carcinogens." [14] Defendants' dismissal of animal studies which have consistently found PCBs to be carcinogenic at all levels of testing is merely a reflection of their desire to dodge the bullet on this issue.

EVIDENCE SUPPORTING THE POSITION THAT PCBS ARE CARCINOGENIC IN HUMANS AND ARE A CONTRIBUTING CAUSE TO THE OCCURRENCE OF HUMAN LUNG CANCER

1. The defendants' attorneys argue that there is insufficient scientific evidence to conclude that polychlorinated biphenyls are carcinogenic. They do not believe that it is more probable than not that PCB and oil and PCDFs and mineral spirits contributed to Mr. Joiner's lung cancer. In my opinion, lung cancer is a probable toxic outcome of exposure to polychlorinated biphenyls. I believe that there is scientific evidence which supports the proposition that polychlorinated biphenyls are carcinogenic, are

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[13] Monro A

How useful are chronic (life-span) toxicology studies in rodents in identifying pharmaceuticals that pose a carcinogenic risk to humans?

Adverse Drug React Toxicol Rev 1993 Spring;12(1):5-34

[14] Huff J

Issues and controversies surrounding qualitative strategies for identifying and forecasting cancer causing agents in the human environment.

Pharmacol Toxicol 1993;72 Suppl 1:12-27

carcinogenic in man, and are able to produce lung cancer in humans.

2. The most recent conclusions of the International Programme on Chemical Safety of the World Health Organization regarding polychlorinated biphenyls are stated in Environmental Health Criteria, No. 140, published in 1993.[15] In this document, the WHO confirms that, "The respiratory tract is certainly the most important route of exposure in the case of acute emergency situations, where unprotected personnel working in areas containing such PCB concentrations may, in theory, inhale a total dose of up to 10 mg/day." They further point out that, "transient irritation of the mucous membranes of the respiratory tract has been reported in emergency situations, as well as difficulty in breathing at high concentrations." They continue on Page 470 with the following statement, "The situation is totally different in the case of acute exposures to heated or decomposed PCBs, in which the inhaled total concentrations might be several orders of magnitude higher than above, though the irritative effect may prevent breathing in such contaminated rooms. Since the soot often contains a considerable fraction of particles, a few microns in size, it is partly breathed in and, thus, may lead to alveolar retention of both soot and absorbed chemicals." [16] The Environmental Health Criteria Document (EHCD) describes precisely the type of exposure which Mr. Joiner underwent. This respiratory exposure, in addition to his dermal exposure, provides further support for the delivery of the PCBs to the target organ, his lung.

In the EHCD, the editors note the significance of a mortality study of PCB workers carried out at the Mon-

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[15] IPCS—International Programme on Chemical Safety Environmental Health Criteria 140: Polychlorinated Biphenyls and Terphenlys.

2nd edition. Geneva: World Health Organization, 1993.

santo plant in Sauget, Illinois by Zack and Musch[16] in 1979. The preliminary report of this study appears in discovery documents provided in connection with this case under the Bates number JOI003183 and following. This epidemiologic study was never published. However, it is cited in the WHO document. Zack and Musch found a general increase in malignancies in the exposed group, 8 observed verses 4.4 expected for an SMR of 179. Lung cancer was elevated, with 4 observed versus 1.44 expected. Although adequate adjustment for confounding because of exposure to additional materials in the workplace was not done, workers who utilized materials quite like those Mr. Joiner used had an elevated incidence of lung cancer.

3. In another study performed by the defendants' in this case in 1975, which they did not furnish to the World Health Organization IPCS, but also appears in the discovery documents associated with this case commencing at Bates number JOI003180, Dr. Mahboubi and his colleagues at the Eppley Institute of Cancer at the University of Nebraska carried out a life table analysis of a group of employees of the Monsanto Krummrich plant, at which PCBs were manufactured.[17] This study which defendants have not published and which is not generally available in the literature but was discovered in the course of this lawsuit, demonstrated, according to Fredrich R. Johansen, staff toxicologist at Monsanto, that, "When compared to the 1969 U.S. male population, this group of 23 deaths would be expected to contain 1.24 cases attributable to lung cancer. Statistical comparison of the observed lung cancer verses the expected lung cancer yielded a highly significant chi x^2 value of 7.1. This number is even more

[16] Zack JA; Musch DC
Mortality of PCB workers at the Monsanto Plant in Sauget, Illinois. Monsanto Chemical Co., St. Louis, MO. 1979. (unpublished report)

[17] Mahboubi E
Correspondence and tables sent to Frederick R. Johannsen, Ph.D., Toxicologist.
Monsanto Company, St. Louis, MO. October 17, 1975.

significant than the value (chi $x^2 = 6.8$) obtained following evaluation of the full 50-person mortality population." [18] Again, defendants' own epidemiologic studies confirm that lung cancer appears in excess in PCB exposed workers.

4. Bertazzi, et al., in an ongoing study of PCB exposed capacitor workers, first published in 1982 and updated several times since, has noted that total cancer deaths were elevated, (12 observed versus 5.3 expected) and that hematological neoplasms were also elevated, (4 observed versus 1.1 expected).[19] Lung cancer was also increased, although, the findings at the time of the last report did not reach statistical significance. Since the cohort under observation has not reached full maturity, it is likely that additional lung cancer cases will occur and that statistical significance will develop in this group of PCB exposed workers also.[19]

5. Observations of Yusho patients, Japanese patients who suffered the adverse effects of consumption of PCB contaminated rice oil, showed elevated SMR's for all malignant neoplasms, including stomach cancers, liver cancers and lung cancers. Statistically significant excess mortality was seen for cancer of the lung.[20]

6. A study of considerable importance to Mr. Joiner's case appeared in the British Journal of Industrial Medicine in 1988, in two parts. These papers by Ronneberg

[18] Johannsen FR
Memo to G. Roush, Monsanto, re: Mahboubi report and tables. Monsanto, Dept. Medicine & Environmental Health, St. Louis, MO. August 27, 1976.

[19] Bertazzi PA; Riboldi L; Pesatori A; Radice L; Zocchetti C
Cancer mortality of capacitor manufacturing workers.
Am J Ind Med 1987;11:165-76

[20] Ikeda M; Kuratsune M; Nakamura Y; Hirohata T
A cohort study on mortality of yusho patients—a preliminary report.
Fukuoka Igaku Zasshi 1987 May;78(5):297-300

and colleagues,[21,22] investigated the mortality and incidence of cancer among oil exposed workers in a Norwegian cable manufacturing company. In Part 2, the mortality and cancer incidence study between 1953-84, a statistically significant excess of deaths from lung cancer in transformer oil exposed workers was observed. Ten deaths from lung cancer were observed where 3.9 were expected. Nine of the cases of lung cancer occurred 20 or more years after first employment, where 2.7 would have been expected yielding a P value of 0.01, a highly significant result. In the subcohort of workers who had at least one year's employment in oil exposed work, there were 7.06 cases of lung cancer per 1,000 person years in smokers compared to 1.30 cases of lung cancer in smokers in the general population sample. It appears that exposure to transformer oil and low viscosity mineral oils were superadditive or perhaps, synergistic carcinogens in these workers. Transformer oils were utilized in impregnation and sheathing from 1940 to 1945 and in installation from 1941 to 1970.

Review of these four studies strongly supports my contention that PCBs do cause lung cancer in humans. In my opinion, PCBs were a significant contributing cause to Mr. Joiner's lung cancer.

MULTI-FACTORIAL CAUSATION OF CANCER

1. Defendants' have suggested that my formulation of the basis for causation of Mr. Joiner's cancer is defective

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[21] Ronneberg A; Skyberg K

Mortality and incidence of cancer among oil exposed workers in a Norwegian cable manufacturing company. Part I. Exposure conditions 1920-79.

Br J Ind Med 1988 Sep;45(9):589-94

[22] Ronneberg A; Andersen A; Skyberg K

Mortality and incidence of cancer among oil exposed workers in a Norwegian cable manufacturing company. Part 2. Mortality and cancer incidence 1953-84.

Br J Ind Med 1988 Sep;45(9):595-601

because it relies upon a "mix" theory. This pejorative term is applied by defendants' attorneys in order to support their belief that plaintiffs experts in general and I in particular should point to a single cause for Mr. Joiner's cancer. Their position flies in the face of scientific knowledge. It defies the current state of the art regarding causation of cancer, and approaches a "junk science" theory.

2. It is uniformly believed by responsible scientists that cancer is a multifactorial and multi-stage process. The exact mechanism by which any type of cancer is caused is still only partially known, but many steps have been defined. This understanding forms the basis for my opinion that Mr. Joiner's cancer is a multifactorial disease, to which PCBs, smoking, family history and other materials contributed.

3. Vainio and Wilbourn in Pharmacology and Toxicology, 1993, indicate that cancer is the result of "both endogenous and environmental factors, ranging from exposure to a single identified chemical to the occupations we follow in order to make our living."[23]

4. Burnstein, in surgical clinics of North America, 1993, indicated that the etiology of colorectal cancer is multifactorial.[24]

5. Correa, in Cancer Research, 1992, indicated that, human gastric cancer is multistep and multifactorial process.[25]

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[23] Vainio H; Wilbourn J

Cancer etiology: agents causally associated with human cancer. Pharmacol Toxicol 1993;72 Suppl 1:4-11

[24] Burnstein MJ

Dietary factors related to colorectal neoplasms.

Surg Clin North Am 1993 Feb;73(1):13-29

[25] Correa P

Human gastric carcinogenesis: a multistep and multifactorial process—First American Cancer Society Award Lecture on Cancer Epidemiology and Prevention.

Cancer Res 1992 Dec 15;52(24):6735-40

6. Lyman, in Primary Care, 1992, in an article on risk factors for cancer commented, "It is no longer reasonable to divide cancers into those that are genetic in origin and those that are environmental in origin. With rare exception, carcinogenesis involves environmental factors that directly or indirectly exert a change in the cell's genome. Virtually all causes of cancer are multifactorial, sometimes involving an inherited predisposition to the carcinogenic effects of environmental factors, which include chemicals, ionizing radiation and oncogenic viruses. Carcinogenesis is a multistep process, including induction, promotion and progression." [26]

7. Jones, et al., in an editorial in the Journal of Cancer Research and Clinical Oncology, 1992, noted that as far as human urinary bladder cancer is concerned, "multifactorial alterations of cellular genes occur." [27]

8. Villa, et al., in the Italian Journal of Gastroenterology, 1991, summarized the multifactorial basis of hepatocellular cancer.[28]

9. Tomatis in IARC Scientific Publications, 1989, presented an overview of perinatal and multigenerational carcinogenesis and commented that, "One of the characteristics of recent decades, which have seen a formidable

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[26] Lyman GH
Risk factors for cancer.
Prim Care 1992 Sep;19(3):465-79

[27] Jones RF; Debiec-Rychter M; Wang CY
Chemical carcinogenesis of the urinary bladder—a status report.
J Cancer Res Clin Oncol 1992;118(6):411-9

[28] Villa E; Melegari M; Scaglioni PP; Trande P; Cesaro P; Manenti F
Hepatocellular carcinoma: risk factors other than HBV.
Ital J Gastroenterol 1991 Sep-Oct;23(7):457-60

expansion of cancer research, has been the co-existence of the generally agreed hypothesis that most cancers are multifactorial in origin . . . ." [29]

10. Kerenyi, et al., in medical hypothesis postulates that one of the multifactorial bases of the increase in the incidence of cancer is "light pollution." In their opinion, "air pollution, smoking, diet, alcohol, occupational exposures and stress are all considered possible etiologic and risk factors" for cancer. They additionally, suggest that light is a significant factor in carcinogenesis because of changes in melatonin production.[30]

11. Higginson, one of the most significant researchers in the field of respiratory carcinogenesis, in a conference proceedings published in 1988, discusses at greath length the issues of multifactorial carcinogenesis in respiratory and total cancer, and their implication for cancer prevention.[31]

12. On the basis of an overwhelming body of scientific evidence which supports the postion which I have taken, that cancer is a multi-factorial disease, I have outlined the elements of causation which are identifiable from Mr. Joiner's family, personal, medical and occupational his-

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[29] Tomatis L
Overview of perinatal and multigeneration carcinogenesis.
IARC Sci Publ 1989;(96):1-15

[30] Kerenyi NA; Pandula E; Feuer G
Why the incidence of cancer is increasing: the role of 'light pollution'.
Med Hypotheses 1990 Oct;33(2):75-8

[31] Higginson J
Multifactorial carcinogenesis significance for cancer prevention risk measurement.
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tory. I have specifically listed these factors in my deposition, I believe that his family history of cancer, his personal history of exposure to cigarette smoke and perhaps to silica, his medical history and his occupational history which included exposure to polychlorinated biphenyls, their contaminants, including polychlorinated bibenzofurans, mineral oil, mineral spirits and other materials together were a sufficient and probable cause of Mr. Joiner's lung cancer. In my opinion, PCBs were a significant contributing cause to Mr. Joiner's lung cancer.

FURTHER THE AFFIANT SAITH NOT.

/s/ Daniel T. Teitelbaum
DANIEL T. TEITELBAUM, M.D.

Sworn to and subscribed before me, on this the 27th day of January, 1993.

/s/ Joan L. Hurley
Notary Public

My commission expires: 11/20/96

Exhibit 1

CURRICULUM VITAE

Daniel T. Teitelbaum, M.D.

Daniel Thau Teitelbaum, M.D., P.C.
155 North Madison
Denver, Colorado 80206
(303) 355-2625

DANIEL THAU TEITELBAUM, M.D.

POSITION:

Clinical Toxicologist, 1988-present
President,
Daniel Thau Teitelbaum, M.D., P.C.
Medical Toxicology & Occupational Medicine

ADDRESS

(BUS): Daniel Thau Teitelbaum, M.D., P.C.
155 North Madison
Denver, Colorado, 80206
(303) 355-2625

(HOME): 2223 S. Alton Way
Denver, Colorado 80231

SCOPE OF PRACTICE:

Clinical Toxicology
Occupational and Environmental Toxicology
Acute and Chronic Poisoning
Analytical Toxicology
Clinical Pharmacology

BORN:

May 26, 1935
New York, New York
Citizenship: U.S.A.

PROFESSIONAL EXPERIENCE:

Qualified Expert Witness in Clinical Toxicology since 1967.

Consultant to the Industrial Commission and State Compensation Fund of Colorado, The United States Food and Drug Administration and the Occupational Safety and Health Administration.

Consultant to industry, agriculture, and labor in occupational and environmental toxicology, including: IBM, CFI Steel, Dresser Industries, W.R. Grace, Coors, Monfort of Colorado. Dynalectron Corporation, Amoco, Xerox, Northern Telecom, Motorola, NCR, TRW, Intel Corporation, Heat and Frost and Asbestos Workers Union, Colorado Construction Trades Council, etc.

Lecturer and seminar leader in all aspects of toxicology practice. Fields of interest: solvents, asbestos, lead, carcinogenesis and biomedical and environmental monitoring.

Extensive experience in the practice of analytical, biomedical and occupational/environmental toxicology. Founder and former director of Poisonlab and Enbionics, independent toxicology laboratories licensed by CDC acredited by AIHA (#60.) Consultant in analytical and clinical toxicology to Bioscience Laboratories and other independent laboratories.

ACADEMIC AFFILIATIONS:

Asociate Clinical Professor of Preventive Medicine, University of Colorado Medical School, Denver, Colorado.

Adjunct Professor of Environmental Sciences, Colorado School of Mines.

Visiting Professor, Medicine and Toxicology, Israel Institute of Technology, The Technion, Haifa Israel.

Scope of teaching: Clinical, occupational and environmental toxicology.

Member of Physicians' Poison Consultation Service	University of Colorado Medical Center, Denver, Colorado

Consultant in Clinical Toxicology — Denver General Hospital and Rockey Mountain Poison Center

CDC licensed Clinical Laboratory Director

1983-1988 Director / Occupational Medicine & Toxicology
Denver Clinic (Accord Medical Center)
701 E. Colfax Ave.
Denver, CO 80203

1982-1983 Staff Physician/Occupational Medicine
Denver Clinic
701 E. Colfax Ave.
Denver, CO 80203

1982-1989 Medical Director, Analytitox Inc.,
Denver, CO

1979-1982 President
Worksafe, Inc.
6825 East Tennessee
Denver, Colorado 80224

1973-1979 President, Poisonlab/Enbionics
Division of Chemed Corporation
1469 South Holly Street
Denver, Colorado 80222

Offices in Denver, San Diego, Cleveland

CLIA #05-1014 AIHA #60

1970-1973 Founder, President, and Toxicology Consultant
Poisonlab, Inc.
1469 South Holly Street
Denver, Colorado 80222

Private Practice—Clinical Toxicology
2045 Franklin Street
Denver, Colorado 80222

1970-1971 Director of Licensed Methadone Treatment Program
IND 6867
2045 Franklin Street
Denver, Colorado 80205

1968-1970 Director of Emergency Services
University of Colorado Medical Center
Denver, Colorado

Assistant Professor of Medicine and Preventive Medicine
University of Colorado Medical Center
Denver, Colorado

1967-1968 Clinical Instructor, Preventive Medicine
University of Colorado Medical Center
Denver, Colorado

EDUCATION:

1956	Bachelor of Arts	Hamilton College Clinton, New York
1960	Master of Hebrew Letters and Rabbi	Jewish Theological Seminary of America
1964	Doctor of Medicine	Albert Einstein College of Medicine
1964-5	Intern, Mixed Medicine	Montefiore Hospital New York City, NY
1965-7	Resident, Internal Medicine	University of Colorado Medical Center, Denver, CO
1967-8	Fellow in Medicine and Toxicology	University of Colorado Medical Center, Denver CO
1991-2	Occupational and Environmental Medicine Program	University of California, San Francisco, CA

COMMITTEES:

Former Member, Toxicology Resource Committee, College of American Pathologists

Former Member, Education Committee, American Academy of Clinical Toxicology

Chairman, United States Food and Drug Administration Advisory Committee on toxicology diagnostic products. (Executive Appointment) 1976-1978

Special Consultant to OSHA, U.S. Department of Labor on Lead, 1977. Participant on behalf of OSHA in lead standards setting hearings

Member, Committee on Operation of Centers, American Association of Poison Control Centers

Chairman, Drug Abuse Committee, American Occupational Medical Association, 1977-1978

Former Member, ASTM Committee E-34 on Safety in the Workplace

Former Member, Board of Trustees, American Academy of Clinical Toxicology

Former Member, Environmental Affairs Committee, W.R. Grace and Co.

Former Member, Chemical Regulations Advisory Committee, Manufacturing Chemists Association

Member, Forensic Sciences Committee of the American Society for Testing and Materials

Member, Occupational Medicine Committee of the American Industrial Hygiene Association

Special Consultant to OSHA, USDOL on Access to Medical Records Standard. 1981

Former Member, State Poison Control Committee, Colorado Department of Health

Former Member, Joint Pesticide Advisory Committee, State of Colorado

Former Secretary-Treasurer to the American Academy of Clinical Toxicology

Former Chairman, Therapeutics Committee, American Academy of Clinical Toxicology

Special Consultant to OSHA, USDOL on Hazard Communication Standard 1982

Special Consultant to OSHA, USDOL on Ethylene Dibromide Standard 1984

Member, Editorial Board, Journal of Toxicology, Clinical Toxicology 1968-1982

Peer Reviewer, Annals of Internal Medicine, 1970-1985

Peer Reviewer, Journal of the American Medical Association, 1975-1985.

Member, Special Blue Ribbon Panel of the Executive Office of the President, National Science Foundation/Council on Environmental Quality on Future Health Implications of Emerging Technologies, 1984

Secretary of the Medical Executive Committee, St. Joseph Hospital, Denver, Colorado 1985-1986

Special consultant, USDOL, OSHA, on Benzene Standard, 1986

SOCIETIES:

American Academy of Clinical Toxicology
American Association of Poison Control Centers
American Academy of Forensic Sciences
The American College of Clinical Pharmacology
American Industrial Hygiene Association
American Society for Testing and Materials
American Academy of Veterinary Toxicologists
American Society of Clinical Pathologists

Forensic Science Society
Rocky Mountain Academy of Industrial Medicine
Occupational Medical Association
Society of Sigma Xi, The Scientific Research Society
Denver Medical Society
Colorado Medical Society
American Association for the Advancement of Science
Society for Risk Analysis

HONORS:

World Health Organization Traveling Fellowship in Clinical Toxicology
Founders Award, American Academy of Clinical Toxicology
Student Fellowship, Jackson Memorial Laboratory, 1952/3
Numerous Academic Prizes in College

BOARD CERTIFICATION:

Board Certified American Board of Medical Toxicology

Recertified by examination, August, 1976

FELLOWSHIPS:

Fellow, American College of Clinical Pharmacology, 1973

Fellow, American Academy of Clinical Toxicology, 1976

PUBLICATIONS:

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INFORMATION AND THE PREVENTION OF GENETIC INJURY, Proceedings, National Safety Congress, 1979.

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CONTACT DERMATITIS, December, 1977.

ANTICONVULSANTS, January, 1976.

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OCCUPATIONAL ASTHMA, September, 1982.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

PLAINTIFFS' RESPONSE TO DEFENDANTS' STATEMENT OF MATERIAL FACTS AND STATEMENT OF MATERIAL FACTS WHICH REMAIN IN ISSUE

DEFENDANTS' FACTS AND PLAINTIFFS' RESPONSE

1.

Robert K. Joiner has worked at The City of Thomasville Water & Light Department ("Thomasville Water & Light") since 1973.

Plaintiffs admit this fact and further show the Court that this has been Robert Joiner's only employment since his graduation from high school. During this employment he was continually and regularly exposed to electrical transformers which were contaminated with dangerous and carcinogenic levels of polychlorinated biphenyls ("PCBs"), polychlorinated dibenzofurans ("dibenzofurans" also sometimes referred to as "PCDF"), and polychlorinated dibenzo-p-dioxins ("dioxins" also sometimes referred to as "PCDD").

2.

As part of his employment at Thomasville Water & Light, Mr. Joiner worked with and around electrical transformers and voltage regulators.

Plaintiffs admit this fact and further show the Court that working on electrical transformers took up over 50% of Robert Joiner's work time. Over 50% of the transformers which have been tested since 1986 have had

levels of PCB in the dielectric fluid to which Mr. Joiner was regularly exposed.

3.

The dielectric fluid contained in the electrical transformers and voltage regulators used by Thomasville Water & light was mineral oil.

Plaintiffs deny that this fact is true and further show the Court that while the dielectric fluid was *supposed* to be mineral oil, more than 50% of the transformers contained levels of PCB contamination which were unsafe and which contributed to the cause of Robert Joiner's lung cancer. This percentage is based only on transformers tested after 1986. Mr. Joiner began working with contaminated transformers in 1973 and it is probable that an even higher percentage were contaminated in the early years of his exposure.

4.

After Thomasville Water & Light began testing its mineral oil-filled equipment for the presence of PCB contamination in 1983, it determined that less than twenty percent of its equipment was contaminated with PCBs.

Plaintiffs deny that this fact is true and further show the Court that more than 50% of the transformers contained levels of PCB contamination which were unsafe and which contributed to the cause of Robert Joiner's lung cancer. The term "contaminated" is a regulatory term as used by Defendants and does not include the numerous transformers which contained PCB but did not qualify as PCB "contaminated" under regulations which govern industry and which are, by their very nature, compromises.

5.

Of all of the equipment tested by Thomasville Water & Light, only about 2.5% of the transformers tested contained levels above 500 ppm, while only about 16.7% of the equipment contained levels above 50 ppm.

Plaintiffs admit that this fact is true for the statistics provided but are unable to admit that it is representative of the percentage of transformers which contained PCB in the earlier years of Mr. Joiner's employment and believe that the percentage would have been higher then. Plaintiffs further show the Court that while the dielectric fluid was supposed to be mineral oil, more than 50% of the transformers contained levels of PCB contamination which were unsafe and which contributed to the cause of Robert Joiner's lung cancer.

6.

The EPA considers any electrical transformer containing less than 50 ppm of PCBs to be a "Non-PCB Transformer" and does not regulate such equipment.

Plaintiffs admit that this fact is true and further show the Court that regulations which govern industry are, by their very nature, compromises and do not relieve Defendants from their duty to prevent the contamination in the first place and then to warn of the contamination once it was known to them. Further, such regulations are irrelevant to measuring Defendants' conduct or duty or liability because Defendants have admitted that there should have been 0 ppm in the supposedly pure mineral oil dielectric. Defendants were well aware of PCB contamination of mineral oil dielectric fluids before Robert Joiner graduated from high school in 1973 and before he was ever exposed to the PCB which caused his injuries.

7.

One (1) transformer at Thomasville Water & Light (not manufactured by either GE or Westinghouse) contained 1,880 ppm PCBs, which was the highest reported level for any transformer or voltage regulator.

Plaintiffs admit that the records which are available show this to be true and further show that regardless of

whether this transformer was manufactured by Defendants GE or Westinghouse, the PCB was certainly manufactured by Defendant Monsanto, the only manufacturer of PCB in the United States. Plaintiffs further show that had Defendants GE and Westinghouse warned of the existence of PCB in their mineral oil dielectric that Plaintiff would have exercised appropriate cautions even when handling the transformers manufactured by other, smaller, less sophisticated manufacturers.

8.

In 1991, Robert K. Joiner was diagnosed with small cell lung cancer.

Plaintiffs admits that Mr. Joiner has cancer of the lung and that he was only 37 years old when diagnosed. However, a description of the particular cancer as being "small cell" cannot be admitted as lung cancer cannot readily be catalogued this simply.

9.

Mr. Joiner smoked cigarettes, and both of his parents smoked cigarettes while he was growing up in their home; thus, according to the plaintiffs' experts, Mr. Joiner had consistent, substantial exposure to cigarette smoke for many years.

Plaintiffs admit that Robert Joiner smoked cigarettes and that his parents smoked cigarettes. Plaintiffs deny that this can be, or has been, characterized as a substantial exposure to cigarette smoke. Plaintiffs further show this Court that Plaintiffs' experts have opined, to a reasonable degree of medical certainty, that cigarettes were merely the initiators of the cancer which is killing Robert Joiner. PCB exposure exponentially increased Robert Joiner's risks of cancer.

10.

Small cell cancer of the lung in humans is caused by tobacco smoke.

Plaintiffs deny this fact to the extent that Defendants seek to imply that tobacco smoke is the only source of the kind of cancer suffered by Robert Joiner. In fact, the kind of cancer suffered by Robert Joiner is associated with various things including exposure to chemicals. Robert Joiner's lung cancer was caused by exposure to PCBs.

11.

According to the plaintiffs' own experts, there is no credible evidence as a scientific probability that PCBs cause or promote small cell lung cancer in humans.

Plaintiffs deny that this fact is true. In fact, the experts retained by Plaintiffs have opined that Robert Joiner's lung cancer was promoted, and thus caused, to a reasonable degree of scientific and medical certainty, by his exposure to PCBs. Further, Plaintiffs' experts have identified to the Court studies which support their opinions as well as reasons, which are beyond the studies, supporting the proposition that PCB promotes and thus causes lung cancer.

12.

According to the plaintiffs' own experts, there are no epidemiological studies which conclude that PCBs cause or promote small cell lung cancer in humans, or, more generally, any form of lung cancer in humans.

Plaintiffs deny that this fact is true. In fact, at least the following studies are instructive on this point and materially contradict Defendants' arguments and support Plaintiffs' position that a genuine issue of fact remains in this case.

Cancer Mortality of Capacitor Manufacturing Workers, Bertazzi et. al., American Journal of Industrial Medicine 11:165-176 (1987)

> "The multiform toxic action of PCBs has been documented in numerous experimental studies, without however, identifying a specific mechanism." 166

> 'Studies of the metabolic fate of these substances in animals sustain the plausibility of a carcinogenic action." 166

> "a previous study [Puccinelli, 1954] showed that less than six months employment could result in substantial exposure to PCBs." 168

> "deaths owing to cancer were significantly higher than expected according to either the national or the local population mortality rates." 169

> "Even the three cases of death from lung cancer were more than expected, but not significantly so." 169

"Table IV. Mortality From Selected Causes of Male Workers Exposed to PCBs"

Cause of death (ICD 8th revision)		National		Local	
	Observed	Expected	SMR	Expected	SMR
Lung Cancer p.170	3	1.2	250	1.6	187"

> **"Analysis by duration of exposure, latency, and year of first exposure did not reveal any definite pattern or trend of mortality for any of the relevant causes." 170**

"Cancer type/ site	*Age at hire(y)*	*Year of hire*	*Length of exposure (y)*	*Latency (y)*	*Age at death (y[)]*
Lung (162)	60	1951	6.7	26	86
Lung (162)	28	1954	.1	7	35
Lung (162) p.171	38	1962	.5	19	57"

Mortality of PCB Workers at the Monsanto Plant in Sauget, Illinois, Zack and Musch, 12/14/79.

> "The SMR for lung cancer was high at 278." JOI 003188

> "There were three deaths observed from lung cancer with 0.94 expected, yielding a SMR of 319." JOI 003188

Table 4

Observed and Expected Deaths. All Males

I.C.D. No. (Eighth Rev.)	Cause of Death	Observed	Expected	SMR
162, 163	Lung	4	1.44	278

Number of persons observed = 89

Table 5

Observed and Expected Deaths, White Males

I.C.D. No. (Eighth Rev.)	Cause of Death	Observed	Expected	SMR
162, 163	Lung	3	0.89	337

Number of persons observed = 60

Table 6

Observed and Expected Deaths, Nonwhite Males

I.C.D. No. (Eighth Rev.)	Cause of Death	Observed	Expected	SMR
162, 163	Lung	1	0.55	182

Number of persons observed = 29

Table 7 shows that all victims of lung cancer had exposures of more than 2 years and four months and less than 3 years.

The Eppley Institute for Research in Cancer was asked by Monsanto to review statistics relating to its workers exposed to PCBs. The results are documented by Dr. E. Mahboubi, MPH, Professor and Head of Epidemiology, at the Institute in letters to Dr. F. R. Johannsen, chief toxicologist for Monsanto:

> Letter of Ocober 17, 1975, page 2:
>
> [T]he lung cancer mortality for these employees, particularly for birth cohorts of 1890-1909, appears to be in excess of what one may expect it to be.
>
> I, as a physician, duly understand your concern for maintaining the confidentiality of these records and I have not duplicated the material. If you wish to have this material returned to you, please so indicate.

> Letter of November 19, 1975, page 1:
>
> The mortality due to lung cancer, however, ranges from betwen three- and ten-fold, when compared to the figure expected, and the increased rate is significant.
>
> Furthermore, all six of the lung cancer victims worked for less than 3 years in the K[rummrich] plant.

In an internal memorandum, Dr. Johannsen had the following to say about PCBs and lung cancer in Monsanto's PCB workers to George Roush, an employee of GE:

Memorandum

From: Dept. of Medicine & Environmental Health—F.R. Johannsen

Date: August 27, 1976 (note this is after the report of Dr. Mahboubi which, though it found lung cancer at high rates, did not think the lung cancer rate was significant.)

Subject: Epidemiology

Reference: Krummrich Plant

In a study of 140 PCB exposed employees, 23 died of all causes and "deaths attributed to lung cancer—4".

> When compared to the 1969 U.S. male population, this group of 23 deaths would be expected to contain 1.24 cases attributable to lung cancer. Statistical comparison of the observed lung cancer versus the expected lung cancer yielded a highly significant cni X^2 value of 7.1. This number is even more significant that the value (cni X^2- 6.8) obtained following evaluation of the full 50-person mortality population.

This gives an SMR of 322!

Ikeda, et. al., *A Cohort Study on Mortality of Yusho Patients—A Preliminary Report*, Fukuoko Acta Med., 78: 297-300, (1987) is a study of Yusho victims exposed to PCBs, as summarized by the World Health Organization's International Programme on Chemical Safety, *Environmental Health Criteria 140, Polychlorinated Biphenyls and Terphenyls (Second Edition)* at page 499, has the following finding:

> "A statistically significant excess mortality was seen for malignant neoplasms, cancer of the liver and cancer of the lung, trachea, and bronchi in males . . . ."

13.

According to a laboratory test of Mr. Joiner's adipose (fat) tissue obtained by Mr. Joiner in 1991 approximately four months after the diagnosis of his small cell lung cancer, Mr. Joiner's body level of PCBs was .3 ppm.

Plaintiffs admit that this is the finding of the laboratory and further show that this finding absolutely shows exposure to PCBs. More significantly, this finding is not believed by any credible scientist as having any meaning or significance as the laboratory work is of questionable quality, (it found no detect levels of dioxins even though dioxins are almost certainly in the tissues of every human in North America), were not properly standardized to World Health Organization or Centers for Disease Control criteria, were taken after radiation, chemotherapy, and rapid weight loss and thus there is no control group to which the measurements have been, or can be, compared. Levels of PCBs, like any other level, are only relevant when compared to norms or expected standards. There are no such standards which include anyone with Mr. Joiner's medical history. Finally, as years had passed since Mr. Joiner's last exposure, it is quite possible that his

levels simply decreased with time—this is a well documented phenomenon in PCB exposure victims.

14.

Mr. Joiner's body level of PCBs, as measured in the analytical laboratory test of Mr. Joiner's adipose tissue, shows that Mr. Joiner's body level of PCBs was slightly less than the average individual in North America who has not had any occupational exposure to PCBs.

Plaintiffs deny that these laboratory results can be used for any valid scientific extrapolation except to show that, assuming that the test was conducted properly, Mr. Joiner positively has PCB in his tissues. PCB does not exist in nature. Only Monsanto manufactured PCB in the United States. Thus, any PCB in Robert Joiner is there because of the conduct of Defendant Monsanto if not all three Defendants.

15.

None of the plaintiffs' expert witnesses can quantify either Mr. Joiner's exposure to PCBs or his dose of PCBs.

Plaintiff deny that this fact is relevant. It is impossible to exactly quantify Mr. Joiner's exposure to PCBs or his dose of PCBs except to note that 50% of his time was spent working on transformers which had been exposed to high heat occurrences including fires. It is not necessary for experts to be able to so quantify exposure so long as exposure occurred—which Defendants implicitly admit must have happened. Further, more than 50% of these transformers were contaminated with some level of PCBs. Given the fact that PCBs are carcinogens, there is no safe level to which Mr. Joiner could be exposed. As an example of the extent of exposure, if a transformer was contaminated with PCBs at only one part per quadrillion (10^{15}) instead of the fifty parts per million (10^{6})

to which he was actually exposed on a regular basis, Mr. Joiner, in a full breath of air in which he would inhale about ten billion trillion molecules, would inhale ten million PCB molecules. (Brown, Michael H., *The Toxic Cloud*, 249-250 (1987))

FACTS WHICH REMAIN IN ISSUE

In addition to the facts set forth above, which remain hotly contested, the following material facts remain at issue and must be resolved by a jury of Plaintiffs' peers.

1.

Whether Defendant Monsanto manufactured all of the PCB to which Robert Joiner was exposed remains in issue.

2.

That Defendants GE and Westinghouse manufactured transformers which contained PCBs to which Robert Joiner was exposed remains in issue.

3.

That the PCB to which Robert Joiner was exposed was contaminated with polychlorinated dibenzofurans, and polychlorinated dibenzo-p-dioxins remains in issue.

4.

That Defendants were aware of the dangers of PCBs and PCDFs and PCDD when Robert Joiner was exposed to these chemicals remains at issue. PCDF and PCDD are expected to be formed when PCB is subjected to high heat and fire remains in issue.

5.

Given Robert Joiner's history of exposure to cigarette smoke he had a very minimal chance of lung cancer at

37 years of age related solely to tobacco smoke exposure remains in issue.

6.

That Robert Joiner suffered lung cancer at 37 years of age because of the known promotional effects of PCBs and PCDFs to which he was exposed remains in issue. That it is more likely than not, to a reasonable degree of medical and scientific certainty, that Robert Joiner's lung cancer was caused by the conduct and chemicals manufactured by Defendants remains in issue.

7.

The credibility of Plaintiffs' experts opinions, and the credibility of the conclusions drawn by them, remain in issue for determination by the jury.

8.

The credibility and weight to be given the studies which demonstrate a positive correlation between exposure to PCBs and lung cancer remains a question for determination by the jury.

9.

The meaning of the Triangle Laboratories adipose tissue results remains a question of weight and credibility to be determined by the jury. (Assuming, of course that Defendants can make a showing that the results are admissible. In all likelihood this showing can not be made because the methodology is seriously flawed.)

10.

That small cell cancer of the lung is humans is a signature disease of exposure to tobacco smoke is a fact remaining in issue.

11.

Mr. Joiner's smoking history is also a fact which remains in issue.

12.

Whether or not valid epidemiological studies exist which demonstrate a positive correlation between exposure to PCBs and lung cancer remains in issue.

13.

Whether or not animal studies can be reasonably relied upon to be indicators of human health efffects remains in issue.

BURGE & WETTERMARK

/s/ Michael J. Warshauer
MICHAEL J. WARSHAUER
Georgia State Bar No. 018720

2700 The Grand
75 Fourteenth Street, Northeast
Atlanta, Georgia 30309
(404) 875-2500

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

AFFIDAVIT OF JOANNE BEAUVOIR BROWN

Personally appeared before me, the undersigned officer duly authorized to administer oaths, Joanne Beauvoir Brown, who after being duly sworn, deposes as follows:

1.

My name is Joanne Beauvoir Brown and I am of the age of majority and am competent to give this affidavit.

2.

The facts stated in this affidavit are based upon my own personal knowledge.

3.

I am an attorney with the law firm of Freeman & Hawkins and along with Joe C. Freeman, Jr., represent Monsanto Company in this matter.

4.

In July, 1993, our office provided to Dr. Anna-Luise A. Katzenstein, M.D. of the State University of New York Health Science Center in Syracuse, tissue slides from the left scalene node biopsy of the Plaintiff in this case, Robert K. Joiner, for her review.

5.

Based upon her review of the stained slides, she was able to confirm the nature of the tumor and support the diagnosis of small-cell carcinoma.

6.

She summarized her diagnosis and findings in her pathology consultation report of which we were provided a copy.

7.

On August 27, 1993, a "meet and confer" was scheduled at the offices of Burge & Wettermark between counsel for Plaintiffs and counsel for Monsanto to address and attempt to resolve disputes which had arisen with respect to certain of Plaintiffs' discovery requests.

8.

In attendance at that meeting were Joe C. Freeman, Jr., and I representing Monsanto and Michael Warshauer and James Holland, II, representing the Plaintiffs.

9.

During the "meet and confer", Joe Freeman and I advised Mr. Warshauer that we had consulted with a pathologist in Syracuse, New York, who had reviewed the tissue slides from Robert Joiner to confirm the diagnosis of small-cell lung cancer.

10.

Joe Freeman told Mr. Warshauer that we had a report from the pathologist confirming that Mr. Joiner had small-cell lung cancer. A true and correct copy of the pathology report is attached as Exhibit "A".

Further, affiant sayeth not.

/s/ Joanne Beauvoir Brown
JOANNE BEAUVOIR BROWN

Sworn to before me this 25th day of February, 1994.

/s/ Diane M. Casey
Notary Public, Fulton County, Georgia
My Commission Expires November 15, 1997

08/03/93
10:26

SURGICAL PATHOLOGY CONSULTATION,
(315) 464-4750
SUNY HEALTH SCIENCE CENTER
DEPT of PATHOLOGY, F.R. DAVEY, MD,
CHAIRMAN
750 EAST ADAMS STREET, SYRACUSE, NY 13210

NAME: JOINER, ROBERT K
PAT#: APC-11949
ACCT: 0000000

PATHOLOGY NO.: S93-05814
PATIENT LOCATION: PVT OUT
ATTENDING PHYSICIAN:
ORDERING PHYSICIAN:

DATE OF SURGERY: NOT GIVEN
DATE RECEIVED: 07/22/93 AGE/SEX: 37Y M
REPORT DATE: 08/03/93 DOB: 01/01/1956

SPECIMEN:

CLINICAL HISTORY: This 37 year old man presented with a mediastinal and left lung mass. A left scalene lymph node biopsy was performed.

DIAGNOSIS: Soft tissue, left scalene area, biopsy—

METASTATIC SMALL CELL CARCINOMA
(see microscopic description)

AAK/Cad

T-1X000 M-80416 CODE: I

GROSS DESCRIPTION:

Four unstained slides (91S-6861) are received from John D. Archbold Memorial Hospital, Thomasville, GA.
AAK/cad

MICROSCOPIC DESCRIPTION:

We performed routine H&E staining on one slide and immunohistochemical staining for cytokeratin, T-cell antigen (UCHL) and B-cell antigen (L26) on the others. The routine H&E stained slide shows a poorly differentiated malignant tumor present within soft tissue. There is extensive crush artifact that makes interpretation difficult. However, the tumor is composed of small cells with dispersed nuclear chromatin pattern and scant cytoplasm. The cells infiltrate between adipose tissue and lack cohesion. The differential diagnosis on the routine stain is between a small cell carcinoma and a lymphoblastic lymphoma. Our immunohistochemical stains show weak staining in the cells for cytokeratin and negative staining for the lymphoid markers. These findings confirm the epithelial nature of the tumor and support a diagnosis of small cell carcinoma.

/s/ Anna-Luise A. Katzenstein, M.D.
ANNA-LUISE A. KATZENSTEIN, M.D.
Attending Pathologist

Also Seen By:
Copy To: Not applicable

MEDICAL RECORD COPY—DO NOT REMOVE

10C *
AND
10CA *
INSULATING
OIL

Characteristics and Maintenance for

- Transformers
- Power Circuit Breakers
- Voltage Regulators
- HR Reclosers
- Oil Switches
- Oil Cutouts

GENERAL ELECTRIC

* * * *

IMPORTANCE OF 10C AND
10CA INSULATING OIL

General Electric's 10C and 10CA oil helps dissipate the heat in induction apparatus; and aids in rupturing the arc in oil circuit breakers. In both cases, 10C and 10CA oil is a major part of the insulation of the apparatus, and this oil is compatible with all materials in the apparatus. (Only 10C and 10CA oil should be used in General Electric apparatus.) Over 60 years of careful observation, research, and development of insulating oils have brought about the high quality and long-life of GE 10C and 10CA oils. The longer an oil can maintain good physical, chemical, and electrical qualities in an apparatus, the less

* *Trademark of General Electric Co.*

the maintenance costs will be for testing the oil. Where quality and durability are concerned, GE 10C and 10CA oil have no equal.

Progressive improvements have been made in the oil over the years. One recent change during 1961 was an increase in flash point of 10C and 10CA oil from 130° minimum to 145C minimum, to provide a greater margin of safety in thermally-uprated transformers.

* * * *

CHARACTERISTICS AND SCREENING SPECIFICATIONS

The following physical, chemical, and electrical properties of 10C and 10CA oils as shipped are controlled to maintain continuity and quality indicated by these tests. Methods for these tests are included in ASTM D117.

Dielectric Strength	Min. 30 kv	Average 35 kv
Flash Point	Min. 145C	Average 150C
Pour Point	Below –40C	Average –54C
Viscosity at 37.8C (Saybolt)	Max. 62 sec	Average 59 sec
Viscosity at OC	Max. 320 sec	Average 290 sec
Specific Gravity. 15.5/15.5C	0.865 to 0.905	Average 0.890
Total Acid Number	Max. 0.02	Average less than 0.01
Color	Max. 0.5	Average less than 0.5
Power Factor. 60 cycle @ 100C	Max. 0.30%	Average 0.1%
Water Content	Max. 30 ppm	Average 20 ppm
Free Chloride Ion	Max. 0.10 ppm	Average none
Free Sulfate Ion	Max. none	Average none
Interfacial Tension, 25C	Min. 40	Average 46
Total Combined Sulfur	Max. 0.15	Average 0.06
Corrosive Sulfur Compounds	Max. non-corrosive	Average non-corrosive
Visual Condition	Clear	Average clear
DBPC Inhibitor Content (for 10CA only)	Min. 0.15	Average 0.17

Note: Additional processing is required for oil to be used in certain high voltage apparatus. These special requirements are covered in such bulletins as GEI 28004, GEI 65070, and GEI 70353.

Charles I. Hubert
professor of electrical engineering
united states merchant marine academy

preventive maintenance of electrical equipment

second edition

McGraw-Hill Book Company
New York St. Louis San Francisco London
Sydney Toronto Mexico Panama

* * * *

2-20 Drying Electrical Insulation

The most favored method of drying insulation is through the application of external heat. This is conveniently done with a regular baking oven, as shown in Fig. 2-18, or by means of an improvised oven of tarpaulin surrounding the machine. A vent at the top of the tarpaulin permits the exit of moisture-laden air. Small machines are often successfully dried by placing them on top of a boiler. When external heat is used for baking, the temperature of the windings should not exceed 90°C as measured by thermometers taped to the coils. The best source of heat for makeshift ovens is an electric heater or radiant-heat lamps; steam heaters or hot-air furnaces also do an adequate job.

Sixty-second insulation-resistance measurements should be recorded every 4 hr during the drying-out process. A typical drying curve for a dc motor armature is shown in Fig. 2-19. During the first part of the drying operation the increase in temperature causes a decrease in the indicated values of insulation resistance. Then, with a constant drying temperature, the resistance increases as the moisture is driven out. When the insulation is dried and allowed to cool, the resistance increases to a high value. The plotted values of insulation resistance are not corrected for temperature, because such correction would serve no useful purpose in this case.

* * * *

INSTRUCTIONS

GEI-32190F

SECONDARY UNIT

SUBSTATION TRANSFORMERS

Oil-Immersed

* * * *

DRYING A TRANSFORMER

After drying the oil in a filter press, the moisture remaining in the windings and insulation can be driven off by heating the transformer. This can be accomplished by shorting one winding and applying a suitable voltage on the other. Full-load current can be obtained by applying the impedance volts of the transformer. *Be sure to load the entire winding.* If the transformer is at room temperature at the start of drying, 125 percent load may be applied until the top oil temperature reaches 65 C. At this point, the current should be reduced in accordance with the following table:

Maximum Allowable Short-circuit Amperes in Percent of Full Load	Maximum Allowable Top Oil Temperature in Degrees C
100	75
85	80
50	85

Since the windings are at a higher temperature than the oil, the insulation may be damaged if these values are exceeded. Filtration during the heat run will not greatly hasten the drying process because at these temperatures the filter press loses its ability to remove any appreciable amount of moisture.

* * * *

FOOD AND DRUG ADMINISTRATION'S REGULATIONS FOR PCBs IN VARIOUS COMMODITIES

Commodity	Allowable Levels (ppm)
Milk	1.5
Manufactured dairy products	1.5
Poultry	3.0
Eggs	0.3
Finished animal feeds	0.2
Animal feed components	2.0
Edible portion of fish/shellfish	2.0
Infant and junior foods	0.2
Paper and packaging material	10.0

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

NOTICE OF APPEAL

Notice is hereby given that Robert and Karen Joiner, Plaintiffs above named, hereby appeal to the United States Court of Appeals for the Eleventh Circuit from the Order dismissing this cause of action dated the 16th of September, 1994.

This 26th day of September 1994.

BURGE & WETTERMARK

By: /s/ Michael J. Warshauer
MICHAEL J. WARSHAUER
Georgia Bar Number 018720

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(Certificate of Service Omitted in Printing)

IN THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 94-9131

ROBERT K. JOINER and KAREN P. JOINER,
Plaintiffs-Appellants,

v.

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
and MONSANTO COMPANY,
Defendants-Appellees.

On Appeal from the United States
District Court for the Northern District of Georgia
Honorable Orinda D. Evans, U.S.D.J.
Dist. Ct. No. 92-02137 1-CV-ODE

JOINT BRIEF OF DEFENDANTS-APPELLEES

February 20, 1995

* * * *

2. *Plaintiffs' Experts' Hypothesis Regarding PCBs is Without Scientific Support.*

Alternatively, the District Court found that, even if plaintiffs' experts "had not made unfounded assumptions about furans and dioxins, defendants still persuade the Court that plaintiffs' expert testimony would not be admissible." 864 F. Supp. at 1322. (R5-69-28) The basis for the Court's alternative ruling was Rule 702, which was construed in *Daubert* to require that the "subject of an expert's testimony must be 'scientific . . . knowledge' . . . which connotes more than subjective belief or unsupported speculation." 509 U.S. at ——, 113 S. Ct. at 2794-96, 125 L.Ed.2d at 480-81 (ellipsis in original; footnote omitted) (*quoted* below, 864 F.Supp. at 1326, R5-69-38-39). After careful consideration of the scientific authorities cited by the plaintiffs' experts, the Court concluded that their leap of faith from inadequate scientific bases to sweeping judgments about the causation of Mr. Joiner's small cell lung cancer constituted an unreliable methodology, and held: "The court need not address whether the studies that plaintiffs' experts rely upon were conducted in a scientific manner, for the studies simply do not support the experts' position that PCBs *more probably than not* promoted Joiner's lung cancer." *Id.* at 1326 (emphasis in original) (R5-69-39). This ruling was fully justified. *See O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090, 1106 (7th Cir. 1994), *cert. denied*, 114 S. Ct. 2711, 129 L.Ed.2d 838 (1994) (expert testimony not reasonably grounded in scientific literature must be excluded as speculative pursuant to *Daubert*); *Turbin v. Merrell Dow Pharmaceuticals*, 959 F.2d 1349, 1360 (6th Cir.), *cert. denied*, 113 S. Ct. 84, 121 L. Ed. 2d 47 (1992) ("[t]he analytical gap between the evidence and the inference to be drawn . . . is too wide") (cited with approval in *Daubert*, 509 U.S. at ——, 113 S. Ct. at 2798, 125 L. Ed. 2d at 484). The District Court criticized not the conclusions reached by plaintiffs' experts, but rather the methodology used to reach

them: unreliable speculation based upon inadequate grounds.

a. *Plaintiffs' Expert Testimony.*

Unquestionably, the most striking evidence supporting the District Court's conclusion that there is no scientific evidence that PCBs promote small-cell lung cancer in humans came from plaintiffs' own expert on the "mechanisms of carcinogenicity," who testified that there is no credible evidence as a scientific probability that PCBs promote small cell lung cancer in humans. Robertson Depo. at 14. Plaintiffs' other experts were also unpersuasive on the point. *See* Teitelbaum Depo. at 110 ("there is no such study"); Schecter Depo. at 68-69 (admitting his opinions are based solely on extrapolations from animal studies). In summary, plaintiffs' experts all agreed that there are no epidemiological studies which conclude that PCBs cause or promote small cell lung cancer in humans. *See* 864 F. Supp. at 1324, n.25. (R5-69-33, n.25) However, the court below did not require epidemiological proof as a matter of law.

b. *Two Studies With Infant, Suckling Mice.*

Instead, the District Court devoted several pages of its thorough opinion to a detailed review of the two experimental *animal* studies cited by the plaintiffs' experts as the scientific underpinning for their hypothesis that PCBs could promote small cell lung cancer in human beings—studies which involved tests on infant, suckling mice first dosed with known carcinogens, then with huge quantities of PCBs (*not* mineral oil contaminated with low levels of PCBs) injected directly into the body cavity containing the most vital organs. 864 F. Supp. at 1322-1326. (R5-69-28-39) The District Court concluded:

> Dr. Robertson admitted that his opinion that PCBs are "promoting agents" is based on only two studies in infant, suckling mice (Robertson Depo., at 14-15). . . . [A]s to those two studies, Dr. Robertson admitted that (1) the lung cancer promoted in the infant mice was not identified as small cell carcinoma (Robertson Depo., at p. 15), (2) he did not know whether the same effect had been produced in adult mice (Robertson Depo., at p. 23), (3) the tumors produced were dose-dependent (Robertson Depo., at p. 26), and (4) after having been administered a known initiating carcinogen, the mice were dosed with 100% PCBs by either injecting it directly into the peritoneum (the body cavity containing the most vital organs) or directly into the stomach (Robertson Depo., at p. 27-28).
>
> A review of the two studies themselves reveals that [the] infant mice developed alveologenic adenomas, not small cell carcinomas (Robertson Depo., Exhibits 2 & 3).

864 F. Supp. at 1322-23 (footnotes omitted). (R5-69-29-30) The District Court further found that "[b]oth Dr. Schecter and Dr. Teitelbaum [also] relied upon the [two] mice studies in opining that PCBs promoted Joiner's lung cancer." *Id.* at 1323 (citing Schecter Depo. at pp. 66-69; Teitelbaum Depo. at p. 48, 78, 81). (R5-69-30) There is no animal study showing lung cancer was promoted in any other species. (Teitelbaum Depo. at 87.)

The District Court held that plaintiffs' reliance on the two infant suckling mice studies was unsound, and revealed that their opinions did not constitute "scientific knowledge," because: (1) there are only two studies (864 F. Supp. at 1322-23) (R5-69-28-32); (2) "the studies obviously used massive doses of PCBs" (*id.*); and (3) Dr. Teitelbaum admitted the mice studies' findings were "preliminary" (*Id.*). Given the nature and limitations of the particular animal studies relied upon by the plaintiffs' experts, the District Court concluded that those studies provided no scientific basis for the opinion prof-

fered by the plaintiffs' experts that PCBs promote small cell lung cancer in human beings.[20]

On this record, the Court concluded that "defendants have sufficiently called into question the validity of plaintiffs' experts' reliance on the mice studies," and held: "Therefore, the burden shifts to plaintiffs to demonstrate by a preponderance of proof that their experts' opinions are admissible." *Id.* at p. 1324 (R5-69-32); *see also* pp. 10-11, *supra*. The Court then gave plaintiffs every opportunity to make such a showing.

Plaintiffs, however, chose "to proceed as if the only issue is whether animal studies *ever* can be a proper foundation for an expert's opinion . . . that is not defendants' argument." *Id.* (emphasis added). Plaintiffs offered nothing more. While the district court properly analyzed plaintiffs' experts' methodology with reference to the specific bases offered as the underpinnings of plaintiffs' experts' proposed opinions in this case, plaintiffs' arguments sought a referendum on the probative value of animal studies in the abstract. The District Court, finding plaintiffs' argument "unresponsive to the issue at hand," ruled that plaintiffs' experts' methodology and opinions were flawed because they "erred in relying on the mice studies to opine that PCBs caused Joiner's lung cancer to a reasonable degree of medical certainty." *Id.* (citations omitted). The studies were too few, too tenuous in application to the present case, and simply inadequate as a basis for the ex-

---

[20] Dr. Teitelbaum testified that in the two studies with infant mice an increase in tumors was observed *only* at the highest dose. (Teitelbaum Depo. Exh. 12-C.) The authors of the studies also recognized the limitations of using infant mice, writing: "further experiments are required to determine whether promotion by PCBs . . . is a special property of tumors initiated soon after birth." In the second study, the authors reported that "exposure also to PCB resulted in a lower tumor incidence in some of the treatment groups" and that "this *protective action was most evident for lung tumors* in both sexes at 18 months of age." (Robertson Depo., Exhibit 2; emphasis added).

perts' opinions, the Court ruled. "The analytical gap between the evidence presented and the inference to be drawn . . . is too wide," the Court wrote. 864 F. Supp. at 1323 (citation omitted). (R5-69-31)

c. *"Epidemiological" Studies Cited by the Joiners' Counsel.*

In Plaintiffs' Opposition to Defendants' Motion, their counsel purported to identify epidemiological studies which they claimed supported their experts' opinions. In discussing these studies, the district court noted with some irony that all three of plaintiffs' experts testified in their depositions that there are no studies showing PCBs cause, contribute to, or promote small cell lung cancer in humans. 864 F. Supp. at 1324, n.25. (R5-69-33, n.25) Still, the District Court carefully considered each of the studies cited by plaintiffs' counsel, and made detailed findings as to why none provided a basis for reaching the conclusion proposed by plaintiffs' experts. The Court found that two studies cited by the plaintiffs reported no statistically significant relationship between PCBs and lung cancer, one revealed "no ground" for any such link, and still another "never mentions PCBs." 864 F. Supp. at 1324-26 (R5-69-33-40) Another showed causation not by PCBs, but by another chemical; even plaintiffs' expert Dr. Teitelbaum called it "not very convincing." *Id.* at 1326 (R5-69-38) (citing Teitelbaum Depo. at 89-90). Based upon this thorough analysis, the District Court concluded: "in every case defendants show that the studies [cited by the plaintiffs] are either equivocal or not helpful. . . ." *Id.* at 1324. (R5-69-34)

The District Court therefore held the plaintiffs' experts' *methodology* inadequate, because there was no scientific link between the cited studies and the proffered opinions:

> [T]he Court is not persuaded by a preponderance of proof that the studies support the "knowledge" the experts purport to have (*i.e.*, that PCBs, "to a 'rea-

> sonable degree of medical certainty,'" *Wells*, 615 F. Supp. at 295, promote small cell lung cancer in humans). *See Turpin*, 959 F.2d at 1360. ("The analytical gap between the evidence presented and the inference to be drawn on the ultimate issue of human birth defects is too wide."); *cf. Wells*, 788 F.2d at 745. ("[T]he basic *methodology* employed to reach . . . a conclusion [must be] sound.")

Id. at 1326 (ellipsis and brackets in original, emphasis supplied). The cases confirm that a district court applying the *Daubert* analysis must exclude proffered expert opinion testimony as methodologically flawed when it is founded upon unreliable bases. In *McLendon v. Georgia Kaolin Co.*, 841 F. Supp. 415 (M.D. Ga. 1994), for example, a District Court in this Circuit applying the *Daubert* analysis stated recently: "The court must make the ultimate determination of whether a reliable basis underlies the expert opinion." *Id.* at 418 (Owens, C.J.) (citing *Smith v. Ortho Pharmaceutical Corp.*, 770 F. Supp. 1561, 1573 (N.D. Ga. 1991)).

The Joiners contend that the District Court improperly rejected the *conclusions* of plaintiffs' experts, rather than the *methodology* used to reach those conclusions. (Appellants' Brief at 14.)[21] This argument ignores what the

[21] The Joiners assert that the District Court opinion states defendants have attacked plaintiffs' experts' "conclusions." (*Id.*) In fact, the District Court wrote: "Defendants . . . attack[] the conclusions that Plaintiffs' experts draw *from the studies they cite.*" 864 F. Supp. at 1322 (emphasis supplied) (R5-69-28). Thus, even the portion of the Court's Order cited by the plaintiffs reflects the District Judge's emphasis on the invalidity of the *leap of faith* from the cited bases for plaintiffs' experts' conclusion to their opinions, rather than the conclusions themselves. As the Third Circuit stated recently in *In re Paoli Railway Yard PCB Litigation*, 35 F.3d 717, 746 (3d Cir. 1994), *reh'g denied*, Oct. 14, 1994, *petition for cert. filed*, Dec. 16, 1994:

> When a judge disagrees with the conclusions of an expert, it will generally be because he or she thinks that there is a mistake at some step in the investigative or reasoning process of that expert. . . This is especially true given that the expert's view that a particular conclusion "fits" a particular case must itself constitute scientific knowledge—a challenge to "fit" is very close to a challenge to the expert's ultimate conclusion about the particular case, and yet it is part of the judge's admissibility calculus under *Daubert*.

Id. at 746 (emphasis in original; footnotes omitted).

Court did. Simply put, the District Court did not reject the conclusions of plaintifls' experts: rather, the District Court analyzed the proffered *bases* for those opinions and correctly concluded that those bases do not constitute scientific support for those opinions. The court looked to (1) the record facts upon which plaintiffs' experts said they relied, (2) the animal studies upon which their counsel said they relied and (3) the epidemiological studies upon which they said they relied, in order to determine whether those facts and studies suported the opinions. It was, in short, the plaintiffs' experts' "methodology" of assuming unproven facts, relying upon limited and questionable animal research, and citing unsupportive epidemiological studies to leap freely to sweeping opinions about causation that the District Court found unscientific and inadmissible.

Because plaintiffs' experts performed no independent research to verify their proffered opinions, reliance upon this leap of faith from inapposite facts and literature *is* their methodology, for they did no more. A methodology which generates opinions based upon inapposite scientific literature is flawed. The District Court properly concluded that, under *Daubert*, because they are without scientific support, "the opinions of plaintiffs' experts do not rise above 'subjective belief or unsupported speculation.'" 864 F. Supp. at 1326 (footnote omitted). (R5-69-39) Plaintiffs' protestations to the contrary notwithstanding, this is a perfectly appropriate basis to exclude the evidence.

Daubert also identifies whether an hypothesis has been tested as the "key question" in determining whether it is derived by the scientific method or is instead speculative and inadmissible. 509 U.S. at ——, 113 S. Ct. at 2796, 125 L. Ed. 2d at 482-83. The plaintiffs' experts' hypothesis *has* been tested and is without scientific support. None of the epidemiological studies support a link between exposure to PCBs and lung cancer in humans, let alone Mr. Joiner's small cell cancer of the lung.[22] Moreover, the epidemiological studies refute the Joiners' hypothesis that PCBs "promote" lung cancer "initiated" by cigarette smoking.[23] In an effort to obscure this fact, plaintiffs' expert Dr. Teitelbaum suggested that the Joiners' hypothesis is "an impossible research question to investigate. . . ." (Teitelbaum Depo. at 110-111.) But,

> "Scientific" knowledge is generated through the scientific method—subjecting testable hypotheses to the crucible of experiment in an effort to disprove them. An opinion that defies testing, however defensible or deeply held, is not scientific.

U.S. v. Bynum, 3 F.3d 769 (4th Cir. 1993), *cert. denied*, 114 S. Ct. 1105, 127 L. Ed. 2d 416 (1994) (citing *Daubert's* emphasis on the testability of proffered expert hypotheses). Indeed, one of the sources cited by the Supreme Court in *Daubert* put the matter very succinctly: "[t]he statements constituting a scientific explanation must be capable of empirical test." *Daubert*, 509 U.S. at ——, 113 S. Ct. at 2796-97, 125 L. Ed. 2d at 483 (quoting C.

---

[22] When all of the epidemiological studies of workers exposed to PCBs (*not* contaminated mineral oil transformers as in this case) are taken together, "you have a body of evidence that doesn't give the slightest inkling that these things [PCBs] cause human cancer." (Cole 10/21/93 Depo., R, Exh. filed 2/2/94 (hereinafter "Cole Depo."), at 88.)

[23] "[If PCBs were assumed to promote lung cancer initiated by cigarette smoking] we would expect some very consequential increase in lung cancer rates. . . . But that hasn't happened." (Cole Depo. at 115, 116).

Hempel, *Philosophy of Natural Science* 49 (1966)). Because the plaintiffs' experts' hypothesis is based upon unsupported premises, is not consistent with the methodology of science, and thus does not constitute "scientific knowledge," the District Court properly excluded the plaintiffs' experts' opinions pursuant to *Daubert*. The District Court's exclusion of plaintiffs' experts' speculative opinions should stand.

* * * *

SUPREME COURT OF THE UNITED STATES

No. 96-188

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners

v.

ROBERT K. JOINER, *et ux.*

ORDER ALLOWING CERTIORARI

Filed March 17, 1997

The petition herein for a writ of certiorari to the United States Court of Appeals for the Eleventh Circuit is granted.

March 17, 1997

No. 96-188

In The Supreme Court of the United States

October Term, 1996

Supreme Court, U.S.
FILED
MAY 30 1997
OFFICE OF THE CLERK

General Electric Company, *et al.*,
Petitioners,

v.

Robert K. Joiner, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF FOR PETITIONERS

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QUESTION PRESENTED

What is the standard of appellate review for trial court decisions excluding expert testimony under *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)?

LIST OF PARTIES

Petitioners in this Court (defendants in the District Court and appellees in the Court of Appeals) are General Electric Company, Westinghouse Electric Corporation, and Monsanto Company. Respondents in this Court (plaintiffs in the District Court and appellants in the Court of Appeals) are Robert K. Joiner and Karen P. Joiner.

LIST PURSUANT TO RULE 29.6

The court is respectfully referred to the List Pursuant to Rule 29.6 that appears at page ii of the Petition for Certiorari herein.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

No. 96-188

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,

v.

ROBERT K. JOINER, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF FOR PETITIONERS

OPINIONS BELOW

The opinion of the District Court is reported at 864 F. Supp. 1310 and appears at P.C.A. 34a.[1] The opinion of the Court of Appeals is reported at 78 F.3d 524 and appears at P.C.A. 1a. The orders of the Court of Appeals denying rehearing and rehearing *en banc* are unreported and appear at P.C.A. 31a and 32a.

JURISDICTION

The judgment of the District Court was entered September 16, 1994. P.C.A. 69a. The judgment of the Court of Appeals was entered March 27, 1996, P.C.A. 1a, and rehearing was denied June 11, 1996, P.C.A. 31a. The petition for certiorari was filed August 5, 1996, and granted March 17, 1997. J.A. 520. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

[1] References to "P.C.A." are to the Appendix to the Petition for Certiorari, to "Br. Opp." to the Brief in Opposition, and to "J.A." to the Joint Appendix. References to "respondent" are to Mr. Joiner.

RULES INVOLVED

Pertinent provisions of the Federal Rules of Evidence, the Federal Rules of Civil Procedure, and rules of evidence of several states are reproduced at pp. 1a-18a, *infra*.

STATEMENT

A. The Complaint.

Respondent, the Chief Electrician for the Water & Light Department of Thomasville, Georgia, was diagnosed with small-cell lung cancer in 1991. J.A. 134, 212, 502. He testified he had smoked cigarettes at the rate of up to a pack a day for at least eight years, beginning when he was a teen-ager and quitting in about 1980 or 1981. J.A. 203-04. Both his parents had smoked; he had lived with them until he was twenty-three. J.A. 203-04; see also J.A. 105, 150-51, 319. His mother had died of lung cancer, as had her brother. J.A. 201-02, 222.

Respondent went to work for the Water & Light Department in 1973, rising by 1985 to Chief Electrician. J.A. 204. One of his duties was to keep the transformers of the city's electrical system in repair. J.A. 205. In addition to paper insulation, the electrical transformers were filled with a "dielectric fluid" of mineral oil, J.A. 366, a mixture of refined petroleum products, which served both as electrical insulation and to reduce heat build-up. J.A. 358-59. Maintaining and repairing the transformers sometimes required draining the mineral oil and drying the coils by slow heat from 1000-watt light bulbs. J.A. 212. Although all the transformers at Thomasville had been manufactured with only mineral oil as dielectric fluid, tests beginning in 1983 showed that in 19.2% of those tested the mineral oil contained PCBs (polychlorinated biphenyls [2]) at levels (50 parts or more per million)

[2] Polychlorinated biphenyls (PCBs) are a group of organic compounds in which biphenyls ($C_{12}H_{10}$) have been chlorinated to varying degrees. Their chemical formula is $C_{12}H_{10-n}Cl_n$ (where n is 1 to 10), and there are 209 possible congeners. Beginning in the 1920's PCBs were put to a number of common industrial uses including electrical applications, sealants, copy paper, printing inks, varnish, paint, and heat-transfer liquids. Like many other chemicals, PCBs in small amounts are detectable at "normal" or "background" levels in most human beings and animals in North America. See generally Kimbrough, *Human Health Effects of Polychlorinated Biphenyls (PCBs) and Polybrominated Biphenyls (PBBs)*, 27 ANN. REV. PHARMACOL. TOXICOL. 87, 87-89 (1987); U.S. DEP'T OF HEALTH, EDUCATION & WELFARE, OCCUPATIONAL EXPOSURE TO POLYCHLORINATED BIPHENYLS (PCBs) 22, 34 (1977); WORLD HEALTH ORGANIZATION, POLYCHLORINATED BIPHENYLS AND TERPHENYLS 19, 39, 195 (2d ed. 1993); J.A. 356-58, 369-70. If eaten, PCBs have an acute toxicity approximately the same as that of ethyl alcohol in beverages, or table salt. CASARETT & DOULL'S TOXICOLOGY 13 (M. Amdur *et al.* 4th ed. 1991); J.A. 375. Most production and distribution of PCBs was prohibited by law effective in 1977. 90 Stat. 2003, 2025 (1976), 15 U.S.C. § 2605(e).

considered significant by the U.S. Environmental Protection Agency. J.A. 389-90; see 40 C.F.R. § 761.3. The source of this contamination was never established. See J.A. 360, 364-65.

After his lung-cancer diagnosis, respondent, who was then aged thirty-seven, filed suit in Georgia state court alleging that "[a]s a result of Plaintiff Robert K. Joiner's exposure to PCBs, he contracted terminal lung cancer," J.A. 21, and seeking compensatory damages exceeding $10,000,000 on each of six counts plus in excess of $20,000,000 punitive damages.[3] Respondent stated that "[t]he nature of my work caused me to inhale PCB fumes and endure the absorption of PCBs through my skin." J.A. 227; see also J.A. 208, 211-13, 228, 230. Named as defendants were petitioners Monsanto Company, which manufactured PCBs until 1977, and General Electric Company and Westinghouse Electric Corporation, which had manufactured mineral-oil transformers, J.A. 19-20, and also until the 1970's some specialized transformers and other equipment with fire-resistant fluid containing PCBs. J.A. 30, 38, 49, 356.[4] The case was

[3] Five counts on behalf of Mr. Joiner alleged negligence, strict liability, and fraud, J.A. 21-25, 27, and a sixth sought damages for loss of consortium on behalf of Mrs. Joiner, J.A. 25-26. Later the complaint was amended to add a claim of battery, also seeking compensatory damages exceeding $10 million. J.A. 74.

[4] Only approximately 0.2% of utility transformers—those designed for specialized uses where fire hazard was a particular concern—had

removed to the United States District Court for the Northern District of Georgia. J.A. 54.

It was undisputed that small-cell lung cancer, with which respondent was diagnosed, J.A. 134, 502, is a disease commonly caused by tobacco smoke, J.A. 105, 109, 261, 276. It was also undisputed that laboratory analysis of respondent's adipose tissue had detected PCBs at a level of only 0.3 to 0.4 parts per million. J.A. 102, 130, 197, 494, which is below that of the average person living in North America (0.5 to 1.5 parts per million). J.A. 115, 154-55, 265-66, 280, 376-77.

B. The Opinions.

The parties informed the District Court that "the central issues in this case relate to causation of Robert K. Joiner's illness," which was a "potentially dispositive issue." J.A. 59. At their joint request, the court stayed discovery on all issues except causation, in anticipation of a motion for summary judgment. J.A. 66. Respondent initially designated Dr. Larry M. Robertson, a toxicologist, as his expert "to testify as to medical causation, specifically, that Plaintiff Robert K. Joiner's exposure to PCBs is a direct and proximate cause of his lung cancer." J.A. 58. However, Dr. Robertson was asked on deposition, "Is there any credible evidence as a scientific probability that PCBs promote . . . small cell carcinoma in the lung in humans," and responded, "I know of none in that context, no, in humans." J.A. 189; see also J.A. 190. Respondent thereafter ceased to rely on Dr. Robertson in opposing summary judgment. J.A. 397. Respondent relied instead on the opinions of Drs. Arnold L. Schecter and Daniel T. Teitelbaum.

Dr. Schecter.—Arnold L. Schecter, M.D., who described his specialty as "preventive medicine" and himself as "uniquely qualified," J.A. 399, 404, conducted a practice focused on persons involved in litigation, particularly claims about PCBs. J.A. 104, 126-27. In an affidavit filed after his deposition, Dr. Schecter stated that "It is my opinion, to a reasonable degree of medical and scientific certainty, that Robert Joiner's exposure to PCB contaminated mineral oil dielectric fluid is the cause of his lung cancer," J.A. 403; that "I eliminated other causes, to a reasonable degree of medical certainty," J.A. 404; and that "[b]ut for Robert Joiner's exposure to PCB contaminated mineral oil dielectric fluid I believe he would not now be suffering from lung cancer," J.A. 403.

Dr. Schecter on deposition had acknowledged that he had met respondent only once, in an attorney's office, and had never conducted a physical examination of him. J.A. 103-05. Dr. Schecter agreed that "Most lung cancer in the United States is caused by cigarette smoking," J.A. 109, explaining that "I believe more likely than not that Mr. Joiner's lung cancer was causally linked to cigarette smoking and PCB exposure." J.A. 107. He stated that "PCBs alone cause cancer," and "I would think that the cigarettes probably served as initiators and that the PCBs, dibenzofurans and dioxins probably more likely than not served as promoters of cancer." J.A. 112.

To support his opinion he cited two studies by a single researcher that had reported that infant mice injected with a known carcinogen and then fed or injected with PCBs had developed liver tumors.[5] J.A. 110.

> "The studies which tell us that PCBs, dioxins and dibenzofurans are promoters of cancer were developed through laboratory animals and we have belief that they are relevant to humans. We test them on animals. We believe that's relevant to humans. . . . I believe that we are in the same kingdom."

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been manufactured with PCBs rather than mineral oil for the dielectric fluid. See 47 Fed. Reg. 17426, 17428 (1982); P.C.A. 85a; J.A. 356, 360-61. None of the transformers at Thomasville was alleged or shown to have been of the kind using any dielectric fluid other than mineral oil.

[5] In the first study suckling mice were injected in their body cavities with N-nitrosodimethylamine, a known carcinogen, after ingesting milk from their mothers, who had been injected with PCBs while pregnant. In the other study infant mice were injected first with N-nitrosodimethylamine and then with a commercial PCB mixture. See J.A. 110, 186-87, 192, 268, 270, 277-78.

J.A. 111. When asked about other mouse experiments that had reported that PCBs actually correlated with reduced incidence of cancer, Dr. Schecter testified "[t]hat could be one interpretation," but dismissed it as perhaps "a statistical fluke." J.A. 121.

Dr. Schecter also rejected other data that did not support his opinion. He acknowledged that the actual analysis of respondent's adipose tissue, by a laboratory selected by respondent, had found a PCB level of only 0.4 parts per million. J.A. 102, 130. He also acknowledged that this did not exceed "what you would expect from an average North American population of healthy adults." J.A. 130, 115-16; see also J.A. 377-78. But Dr. Schecter criticized the laboratory's findings on the basis that he did not believe the result. J.A. 129-30, 123-24, 407. Although he conceded that the mouse experiments had reported liver tumors "in a dose dependent fashion," J.A. 112, he testified that "I have no opinion" about how much PCBs respondent had absorbed, J.A. 118; see also J.A. 128-30. He said he assumed that respondent must have had a high exposure based on "[t]he fact that he worked with these chemicals," J.A. 113, but "I cannot quantify the exact amount." J.A. 115. Ultimately he testified that in his opinion the size of dose did not matter, J.A. 133, and that he believed that PCBs could cause injury even at doses below background levels. J.A. 116.[6]

Although the complaint and amended complaint alleged only PCBs to be the cause of respondent's small-cell lung cancer, J.A. 19-28, 67-77, Dr. Schecter also testified that it could have been caused or promoted by dioxins or furans,[7] which he assumed also had been present even

[6] Dr. Schecter also offered what he termed "[m]y assumption," J.A. 131, that respondent's level might have been higher before medical treatments—although "I can't cite you anything" as support. J.A. 132. Dr. Teitelbaum, respondent's other expert, called such an assumption "pure speculation," "absolutely a guess." J.A. 155; *cf.* J.A. 374-75.

[7] Polychlorinated dibenzodioxins ("PCDDs" or "dioxins") and polychlorinated dibenzofurans ("PCDFs" or "furans"), like

though there was no evidence of their presence in the transformers at Thomasville, J.A. 132-33, or at abnormal levels in respondent's body, J.A. 102, 123, 378-79, 385. Just as with PCBs, Dr. Schecter could identify no studies concluding that furans or dioxins could cause small-cell lung cancer in human beings. J.A. 109-12.

To explain his assumption of exposure to dioxins or furans, Dr. Schecter offered the opinion that PCBs at some high temperature would oxidize and form dioxins or furans; however, he explained that he was not a chemist, J.A. 109, and did not know what temperature would be required, J.A. 122-23, 132. He added that "I don't memorize temperatures, I don't memorize numbers." J.A. 126. In his later affidavit he cited a treatise that he said stated that furans could be produced when PCBs burned, and he said that dioxins and furans had been detected at the scene of a transformer fire in New York. J.A. 405.

Dr. Teitelbaum.—Daniel T. Teitelbaum, M.D., a toxicologist, testified that he heads a corporation with sixteen employees including a full-time paralegal, J.A. 136, 168-69, 170-71, testifies three to four times per month at a charge of $4,000 per day, J.A. 168, "almost always, I would say, for the plaintiff," J.A. 167-68, and has so much business that he does not need to advertise. J.A. 171. Dr. Teitelbaum offered the opinion that respondent's small-cell lung cancer "was caused by or contributed to in a significant degree by the materials with which he worked," J.A. 140, by which he meant, he said, mineral spirits, paints, and mineral oil containing PCBs. J.A. 149-50, 153. However, when asked "is there any study that you know of anywhere in humans that indicate[s] that small-cell, being specific to this diagnosis, lung cancer was caused by PCBs?" he responded:

> "No. It's an impossible research question to investigate, I think, in the first place, and in the second place, there is no such study."

PCBs, are halogenated hydrocarbons. They also are environmentally ubiquitous at background levels, J.A. 266-67, 279, and no studies have concluded that at such levels they are carcinogenic in human beings. J.A. 266-67, 275, 308, 316, 376, 382.

J.A. 169. His answer was the same when asked whether there was any study showing that PCBs could contribute to or promote such cancer. J.A. 170.

Dr. Teitelbaum agreed that respondent's actual tested PCB level was not above the normal background range. J.A. 154-55. But he opined that "I don't think that there is any way of relating the quantity of PCBs measured in anything with any outcome." J.A. 153.[8] He noted "some discrepancy among" respondent's "various medical records," J.A. 144; some prepared prior to the litigation showed respondent to have smoked up to two packs of cigarettes per day for fifteen years, J.A. 106, 134, 143-44, 173, 265, 313. Dr. Teitelbaum acknowledged that respondent's history of smoking, having lived with smokers, and lung cancer of close relatives were "part of the mix." J.A. 146-47, 150-51. But when asked whether respondent's cancer was initiated by respondent's cigarette smoking, he responded that "That would be purely speculative." J.A. 148.

Asked for epidemiological evidence to support his opinion, he testified that, although he believed researchers are "willing now to take the position that PCBs are human carcinogens,"

> "I don't think that they would—any of them would be willing to say that they have evidence, convincing evidence, that PCBs cause any single kind of cancer."

J.A. 161. What he called "the best study" suggesting causation, J.A. 161, he acknowledged, was "not statistically significant," J.A. 163, but "the simple fact that it did not reach statistical significance isn't enough to convince me the study is not right," J.A. 164.[9]

[8] A few minutes earlier, however, Dr. Teitelbaum had testified that "I am a firm believer in the concept that if there is more carcinogen exposure, there is more risk of cancer." J.A. 147. *Cf. Sweger* v. *Texaco, Inc.*, 930 F.2d 35 (table), 1991 U.S. App. Lexis 8572 (10th Cir. 1991) (affirming district court's rejection of opinion of Dr. Teitelbaum that exposure to a single molecule of motor oil could have caused cancer).

[9] Dr. Teitelbaum also referred to "the expert committee that IARC [International Agency for Research on Cancer] had together,

When asked whether any animal study of PCBs had reported small-cell lung cancer, he responded that

> "I don't think there's an analogy in animals that would be relevant, so I can't point to such a study."

J.A. 170. He cited the same two mouse studies relied on by Dr. Schecter as showing that PCBs were "known to be an animal carcinogen." J.A. 147, 158-60. But, he concluded,

> "so that's as far as we can go. Whether the same thing would be present in other animals, I can't conclude from her study . . . ."

J.A. 158; see also J.A. 160.

Dr. Teitelbaum assumed that respondent had been exposed to PCBs because it was "reasonable to assume," J.A. 142, "a reasonable assumption," J.A. 143, J.A. 145, 155-56. He also, like Dr. Schecter, "assume[d] that there was some furan present, that there may have been some dioxin present." J.A. 143. However, he had "no quantitative analyses . . . that answer how much and when," *id.*, and questions about possible formation of other chemicals from PCBs he said were "outside the scope of my expertise." J.A. 156. Nevertheless, he later opined that furans must have been produced because fumes had been observed and some transformers brought for repair had been damaged in fires. J.A. 406.

C. Challenge Under Rule 702.

Petitioners argued to the District Court that "[a]s admitted by plaintiffs' own experts, their opinions are not

and their conclusion was there's enough evidence to say that it's probably a human carcinogen, there is not enough evidence to say that is proved, and I think I would have no problem accepting that." J.A. 165. An epidemiologist and a toxicologist explained that even that statement was only by a "workshop" group which had not presented any scientific findings, and that the IARC of the World Health Organization was not a body that took positions on scientific issues. J.A. 236-37, 278. The same 1993 World Health Organization document that mentioned the workshop group advised that "Overall, there is reason to exercise caution in extrapolating the available animal data on the carcinogenic potential of PCBs to humans." WORLD HEALTH ORGANIZATION, *supra* n.2, at 37; *cf. id.* at 478.

based on credible scientific evidence and are therefore speculative," J.A. 387, and also depended on unsupported assumptions that "did not 'fit' the facts of the case." J.A. 388. Asking exclusion of the opinions for failure to satisfy the standards for admissibility of Fed. R. Evid. 702 as explained in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), petitioners moved for summary judgment. J.A. 98.

To confirm further the absence of any scientific support for the causation opinions, a toxicologist, William J. Waddell, M.D., of the University of Louisville Medical School, testified (as had Dr. Teitelbaum, J.A. 158, 170, and Dr. Robertson, J.A. 188-90) that scientific methodology does not permit the conclusion from two studies of infant mice injected with a known carcinogen that PCBs are capable of causing or promoting small-cell lung cancer in human beings. J.A. 265, 267-68, 270. He also testified, based on review of the scientific literature, that "[t]here is no evidence that PCBs cause cancer" in human beings, J.A. 271, "no information in humans that PCBs cause cancer of the lung at whatever dose." J.A. 279. By contrast, he noted, "I don't think that there is any reasonable scientist that would deny that cigarette smoking causes lung cancer." J.A. 273; see also J.A. 276, 279.

An epidemiologist, Philip Cole, M.D., Dr.P.H., testified after reviewing the existing studies and data that "Here you have a body of evidence that doesn't give the slightest inkling that these things [PCBs] cause human cancer," J.A. 238, adding that he knew of no scientist who believed that they do, J.A. 234-35. On the other hand, epidemiological data show "there's a massive association between SCLC [small-cell lung cancer] and cigarette smoking." J.A. 239.

Finally, Professor William Charles Bailey, M.D., of the University of Alabama Medical School, a pulmonary specialist, testified that "I looked specifically, is there really even any circumstantial evidence that small cell cancer, which is what this man has, could be caused by PCB and

found no evidence, even circumstantial or partial or, you know, inconclusive that that might be considered." J.A. 307; see also J.A. 317, 320. Nor, he testified, did any scientific evidence exist that dioxins or furans could be such a cause, an observation confirmed by Drs. Waddell and Cole. J.A. 233, 267, 308, 316. He explained that the method by which animal studies are used in medical science is that "before you can really draw any conclusions about humans, you have to have data on humans, obviously, because they're different." J.A. 306. Referring to "the overwhelming evidence that small cell cancer is exclusively caused by cigarette smoking," he explained that "it's so clear that small cell cancer is caused by cigarette smoking, and there was not even any circumstantial evidence in the literature that it might be related to PCB." J.A. 308; see also J.A. 309-10, 317, 348, 350-51. Dr. Bailey also noted epidemiological data that 4,000 to 5,000 Americans aged in their thirties or younger die of lung cancer each year. J.A. 311, 315, 354.

D. The District Court's Ruling.

On the issue of PCB exposure, the District Court ruled for respondent, holding that "the court finds that a genuine dispute exists over whether Joiner was exposed to PCBs." P.C.A. 44a. But it held that under Rule 702 respondents had failed to present admissible evidence of causation, or of exposure to furans or dioxins. P.C.A. 49a, 51a, 68a.

1. *Absence of Epidemiological Evidence.*—Although some courts have held epidemiological studies essential to support opinions of causation of human disease,[10] the District Court ruled that "the absence of an epidemiological study in Plaintiffs' favor does not automatically foreclose their action." P.C.A. 58a. But the District Court found

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[10] *E.g.*, *In re Joint E. & S. Dist. Asbestos Litigation*, 52 F.3d 1124, 1128 (2d Cir. 1995); *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 313 (5th Cir. 1989), *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990); *In re "Agent Orange" Product Liab. Litigation*, 611 F. Supp. 1223, 1239 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied sub nom. Lombardi* v. *Dow Chem. Co.*, 487 U.S. 1234 (1988); *cf.* J.A. 274-76.

that the epidemiological studies relied on by respondent "in every case . . . are either equivocal or not helpful" and "simply do not support the experts' position." P.C.A. 63a, 67a.[11]

2. *Absence of Relevant Animal Studies.*—The District Court specifically declined to hold that animal studies could never support an opinion of disease causation in human beings. P.C.A. 60a, 62a.[12] It held, however, that the two studies of mice cited by Drs. Teitelbaum and Schecter lacked the requisite "fit" under Rule 702 to support the opinion that PCBs had caused respondent's small-cell lung cancer. P.C.A. 62a. It noted that there were only two studies, concededly they were only preliminary, P.C.A. 61a, J.A. 186-87, 160, that they involved applica-

[11] The District Court noted, for example, that one of the epidemiological studies itself advised that "[t]he numbers were small, the value of the risk estimate was not statistically significant, and such risk had never been suggested before." P.C.A. 63a. In the second the authors also "specifically stated that '[w]hile many of the cancer-specific SMRs exceed 100, none are statistically significant.'" P.C.A. 64a. The third study did not involve exposure to PCBs at all. P.C.A. 64a-65a. The fourth was not an epidemiological study but a preliminary analysis, and involved not inhalation but ingestion, of toxic rice oil containing furans and other chemicals in addition to PCBs. P.C.A. 65a-66a. Respondent's own expert had testified it was "not very convincing." P.C.A. 66a, quoting J.A. 161.

[12] *But see, e.g., Lynch* v. *Merrell-National Labs.*, 830 F.2d 1190, 1194 (1st Cir. 1987) (animal studies "do not have the capability of proving causation in human beings in the absence of any confirmatory epidemiological data"); *Viterbo* v. *Dow Chem. Co.*, 826 F.2d 420, 424 (5th Cir. 1987) (holding animal study cannot support opinion of human carcinogenicity); *In re "Agent Orange" Product Liab. Litigation, supra*, 611 F. Supp. at 1241 (holding animal studies unacceptable under Rule 703 as basis for opinion of human causation, and inadmissible under Rules 401, 402 and 403); *Bell* v. *Swift Adhesives, Inc.*, 804 F. Supp. 1577, 1580 (S.D. Ga. 1992) ("Nothing in the record persuades this Court to depart from the precedent set in Georgia federal district courts as well as in other circuits by viewing animal studies favorably"). "In 'toxic tort' cases, courts have generally insisted on epidemiological data . . . . Animal studies, particularly those with questionable relevance to humans, carry relatively little weight." K. FOSTER & P. HUBER, JUDGING SCIENCE 133 (1997).

tion of massive doses of PCBs to suckling mice that already had been injected with a known carcinogen, P.C.A. 59a, 61a, J.A. 193-94, and that nevertheless none of the mice developed small-cell lung cancer. P.C.A. 59a, J.A. 189. It found that in medical methodology the fact that a substance can cause some form of cancer in mice may indicate a reason for future study, but is not regarded by scientists as establishing that it is carcinogenic in human beings. P.C.A. 61a-62a; see J.A. 111, 169-70, 265, 267-70, 306.

3. *Absence of Evidence of Other Chemicals.*—The court held that even assuming that other chemicals could be formed in some conditions from PCBs,[13] the District Court held "[i]t is also Plaintiffs' task to link that evidence to the facts of this case, i.e., to show some credible evidence that the City's transformers were exposed to a temperature hot enough to generate furans." P.C.A. 48a. The Court noted that there had been no data at all that furans or dioxins had been found in any of the transformers with which respondent worked; that the laboratory tests of respondent's tissue had shown no abnormal level of dioxins, and had found no detectable level of furans in his body at all. P.C.A. 44a-45a; see J.A. 117-18, 197, 407. The court held it inadequate simply to say that some transformers sent for repairs had experienced fires, or that when some were heated by light bulbs, fumes had been observed. P.C.A. 48a; see J.A. 212-13. "Thus, the testimony of Plaintiffs' experts manifestly does not fit the facts of this case, and is therefore inadmissible." P.C.A. 57a.

4. *"The Analytical Gap."*—Emphasizing that to satisfy Rule 702 "[t]he basic methodology employed to reach . . .

[13] The only expert testimony from chemists was that no evidence existed that PCDDs (dioxins) could be formed from PCBs under any conditions, J.A. 360, 367, 370, that formation of PCDFs (furans) even at extremely high temperatures from pure PCBs was unlikely even in insignificant amounts, J.A. 361, 365, 371, and that the dilution of tiny amounts of PCBs in mineral oil would make such formation "extraordinarily unlikely," J.A. 365; see J.A. 361-62, 371. The only test of mineral oil from a transformer at Thomasville that had caught fire showed only 26 ppm (parts per million) PCBs. J.A. 225-26. See pp. 36-37, *infra*.

a conclusion [must be] sound," the District Court concluded that "the studies simply do not support the experts' position that PCBs *more probably than not* promoted Joiner's lung cancer;" "[t]he analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue . . . is too wide." P.C.A. 67a (emphasis in original).[14] It pointed out that even Dr. Teitelbaum testified that "he was aware of no studies which show that PCBs cause, contribute, or promote small cell lung cancer in humans." P.C.A. 62a n.25, citing J.A. 169-70. It noted that Dr. Schecter could cite no authority except the two mouse studies, which had not observed small-cell lung cancer, and that even Dr. Teitelbaum, confirmed by Drs. Waddell and Bailey, had testified that "I don't think there's an analogy in animals that would be relevant." J.A. 170; see J.A. 265, 270, 306. Holding that "the opinions of Plaintiffs' experts do not rise above 'subjective belief or unsupported speculation,'" P.C.A. 67a (quoting *Daubert*, 509 U.S. at 590), the District Court excluded the opinions and granted summary judgment. P.C.A. 68a.[15]

E. The Court of Appeals' Reversal.

In a 2-1 decision, the Court of Appeals reversed. It began by announcing that

> "Because the Federal Rules of Evidence governing expert testimony display a preference for admissibility, we apply a particularly stringent standard of review to the trial judge's exclusion of expert testimony."

P.C.A. 4a. As authority it cited the opinion of the Third Circuit in *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 750 (3d Cir. 1994), *cert. denied sub nom. General*

[14] Quoting in part *Wells* v. *Ortho Pharmaceutical Corp.*, 788 F.2d 741, 745 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986), and *Turpin* v. *Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir.), *cert. denied*, 506 U.S. 826 (1992).

[15] The court added that even if the opinions were admitted, "no reasonable juror could find that PCBs caused Joiner's lung cancer given the flawed nature of Plaintiffs' experts[']' opinions." P.C.A. 67a n.29; *cf. Daubert*, 509 U.S. at 596.

Elec. Co. v. *Ingram*, 115 S. Ct. 1253 (1995). Using that "particularly stringent standard of review," the Court of Appeals proceeded to examine the record itself.

Turning first to Rule 702's requirement of reliability, the Court of Appeals held that "the extensive experience and specialized expertise of each of these experts augment the reliability of their reasoning and methodology," P.C.A. 11a, and that "each utilized scientifically reliable methods," *id.* at 10a. It accepted the statements in Dr. Teitelbaum's post-deposition affidavit that "I utilized traditional medical assessment techniques" and "I also relied upon my extensive experience." *Id.* at 9a; see J.A. 450. It also pointed out, citing another post-deposition affidavit, that "[i]n arriving at his opinion, Schecter claimed to have eliminated other potential causes of Joiner's lung cancer to a reasonable degree of medical certainty." P.C.A. 10a; see J.A. 404. The Court of Appeals emphasized (without examining the contents) that "the Joiners' experts discussed the studies of at least thirteen different researchers." P.C.A. 12a. With respect to the two mouse studies, it held that "[t]he number of studies is irrelevant," that "it is improper to find research unreliable solely because it uses animal subjects," *id.*, and that unless the studies themselves were somehow flawed, conclusions Dr. Schecter said he drew from them were admissible. *Id.* at 13a-14a.

The Court of Appeals added that the District Court should not have excluded the opinions of the two medical doctors that assumed exposure of respondent to dioxins or furans. The Court of Appeals said that it had been petitioners' burden to present evidence of the temperatures of the drying process and of a fire, and to show that such chemicals had not been produced. P.C.A. 15a-16a. The Court of Appeals also said that furans might have been formed when one transformer had been struck by lightning. *Id.* at 16a.[16]

[16] Judge Birch concurred briefly, urging that it would be better for trial courts to appoint "a competent, independent and philosophically neutral Rule 706 expert." P.C.A. 17a.

F. The Dissent.

Judge Smith in dissent reasoned that there should be "deference to the trial court's admissibility determinations," P.C.A. 20a n.1, and that

> "an expert's testimony does not 'assist' the trier of fact if the expert does not explain the steps he took to reach his conclusion. We should not require the trier of fact to accept blindly the expert's word to fill the analytical gap between proffered 'scientific knowledge' and the expert's conclusions. Therefore, the trial court 'gatekeeper' has broad discretion to decide whether a leap of faith across the analytical gap is so great that, without further credible grounds, the testimony is inadmissible."

P.C.A. 17a-18a. "It is incumbent on the proponent of scientific evidence to fill the analytical gap between a proffered study and the particular facts of the case (i.e., 'fit')." P.C.A. 26a. The dissent challenged the majority's reliance on general references to unsupporting epidemiological studies, P.C.A. 28a, and pointed out that "[t]he trial court's ruling was not that animal studies are inadmissible *per se*, but that Mr. Joiner's general response that experts generally rely on animal studies fails to show the reliability and 'fit' of these particular animal studies." P.C.A. 25a. Regarding dioxins or furans, the dissent explained that "I am not prepared to reverse the trial court on this issue because it is Mr. Joiner who has the burden of proving admissibility." P.C.A. 23a. "[S]ifting through the expert's testimony is a crucial 'gatekeeping' function," P.C.A. 22a, and "I would approve the trial court's step-by-step approach," P.C.A. 30a. "[A]n expert may not bombard the court with innumerable studies and then, with blue smoke and sleight of hand, leap to the conclusion." P.C.A. 22a.

SUMMARY OF ARGUMENT

The Court of Appeals here embraced a new "particularly stringent" standard of review under Rule 702 that is inconsistent with the Federal Rules and with this Court's holdings that "A district court is accorded a wide discretion in determining the admissibility of evidence under the Federal Rules." *United States* v. *Abel*, 469 U.S. 45, 54 (1984). "[T]he District Court has wide discretion in its determination to admit and exclude evidence, and this is particularly true in the case of expert testimony." *Hamling* v. *United States*, 418 U.S. 87, 108 (1974).

Rule 702 of the Federal Rules of Evidence requires that "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993). Rule 702 assigns district judges "a gatekeeping role." *Id.* at 597; see also *id.* at 600 (Rehnquist, C.J., concurring and dissenting) ("I do not doubt that Rule 702 confides to the judge some gatekeeping responsibility . . . .").

If a district court ignores or misconstrues the governing law—as by, for example, failing to follow Rule 702's criteria of reliability and relevance, as set forth by this Court in *Daubert*—then it has committed an error of law, subject to plenary review and reversal on appeal. See, *e.g.*, *Cooter & Gell* v. *Hartmarx Corp.*, 496 U.S. 384, 402 (1990); *Icicle Seafoods, Inc.* v. *Worthington*, 475 U.S. 709, 714 (1986). But in the ordinary case, when as here the prescribed legal rule has been applied, the standard of appellate review of evidentiary rulings is deferential, reflecting a district court's "wide discretion."

Ten circuits since *Daubert* have reaffirmed that rulings admitting or excluding evidence under Rule 702 will be reversed only for "abuse of discretion" or "manifest error." The Eleventh Circuit here, adopting a 1994 decision by the Third Circuit, departed from the established standard to apply a new, judicially created, "particularly stringent" review—but only for rulings that exclude proffered opinions and lead to summary judgment. Such a new result-

oriented standard of review has no grounding in the text or history of Rules 104 or 702. It is contrary to more than a century of decisions by this Court and others according broad deference to trial courts' rulings on expert testimony. And it undermines the command of Rule 702, which this Court recognized in *Daubert*, that district courts are to exercise a "gatekeeping" function, to protect the factfinding process from opinions that are not reliable as science or do not fit the facts of the case being adjudicated.

Such a novel one-way result-oriented standard of review also bears no relation to the criteria for determining standards of review that this Court has set forth repeatedly: applicable text; historical practice; and functional appropriateness, including which level of court is best situated to decide, and whether detailed review by appellate courts would make sense in terms of their function of clarifying legal doctrine. To invent yet another standard of review would further burden appellate courts, while ignoring this Court's caution that it is "undesirable to make the law more complicated by proliferating review standards without good reasons." *First Options of Chicago, Inc.* v. *Kaplan*, 115 S. Ct. 1920, 1926 (1995). It would not improve results; in the present case, for example, the District Court had overwhelming basis for ruling as it did, and the Court of Appeals did not master the record. See pp. 35-38, *infra*. And by operating only when opinion testimony is excluded and summary judgment results, this one-way standard would undermine the policy of Rule 56, Fed. R. Civ. P., that summary judgment is not to be disfavored. See *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 327 (1986). Asymmetrical "particularly stringent" review not only is unsupported in the Federal Rules and contrary to *Celotex* and *Daubert*, but also would ignore the even-handedness that normally characterizes this country's judicial procedure.

ARGUMENT

I. THE FEDERAL RULES AND WELL-ESTABLISHED PRECEDENT CALL FOR BROAD DISCRETION FOR DISTRICT COURT RULINGS ON ADMISSIBILITY OF EXPERT TESTIMONY.

A. The Federal Rules of Evidence Assign the District Courts Broad Discretion To Rule on Admissibility of Expert Testimony.

1. *Rule 104(a) Provides for Broad Discretion.*

Admissibility determinations for scientific opinions are preliminary matters decided by the trial judge pursuant to Rule 104(a) of the Federal Rules of Evidence.[17] *Daubert*, 509 U.S. at 592 & n.10. Rule 104(a) is remarkable for the exceptional latitude it allows trial judges in ruling on admissibility of testimony. It provides simply that such questions "shall be determined by the court." It sets no particular procedures or methods limiting how the trial court arrives at such rulings; in fact, the Rule goes out of its way even to provide that except as to privileges, a district court in making admissibility rulings "is not bound by the rules of evidence."

> "The Rule on its face allows the trial judge to consider any evidence whatsoever, bound only by the rules of privilege."

Bourjaily v. *United States*, 483 U.S. 171, 178 (1987). *Accord*, Fed. R. Evid. 1101(d).

"F.R.E. 104 retains the principles . . . developed at common law." *United States* v. *Sliker*, 751 F.2d 477, 498 (2d Cir. 1984) (Friendly, J.), *cert. denied*, 470 U.S. 1058, 471 U.S. 1137 (1985). "[T]he common law rule was that the judge and not the jury should decide 'any preliminary questions of fact, however intricate, the solution of which may be necessary to enable him to de-

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[17] Fed. R. Evid. 104(a) provides:

"Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court . . . . In making its determination it is not bound by the rules of evidence except those with respect to privileges."

termine . . . the admissibility' of evidence." 751 F.2d at 497, quoting J. THAYER, PRELIMINARY TREATISE ON EVIDENCE 258 n.3 (1898) (quoting *Gorton* v. *Hadsell*, 9 Cush. 508, 511 (Mass. 1852)).

A provision that "emphasizes the fact that the determination is for the district court to make . . . thus suggests some deference to the district court upon appeal." *Pierce* v. *Underwood*, 487 U.S. 552, 559 (1988). See also, *e.g.*, *Wilton* v. *Seven Falls Co.*, 115 S. Ct. 2137, 2144 (1995) (abuse-of-discretion standard adopted because in applying Declaratory Judgment Act it is "more consistent with the statute to vest district courts with discretion in the first instance"); *Koon* v. *United States*, 116 S. Ct. 2035, 2046 (1996) ("A district court's decision to depart from the [Sentencing] Guidelines . . . will in most cases be due substantial deference, for it embodies the traditional exercise of discretion by a sentencing court"). What a provision embodying trial-court discretion does not contemplate is for a court of appeals to "substitute[] its own judgment for that of the District Court." *Piper Aircraft Co.* v. *Reyno*, 454 U.S. 235, 257 (1981) (*forum non conveniens* determination). *Cf.* also, *e.g.*, *Braun* v. *Lorillard Inc.*, 84 F.3d 230, 237 (7th Cir.) (exclusion of hearsay under Rule 803 reviewed for abuse of discretion), *cert. denied*, 117 S. Ct. 480 (1996); *United States* v. *Matta-Ballesteros*, 71 F.3d 754, 767 (9th Cir. 1995) (same), *amended*, 98 F.3d 1100 (9th Cir. 1996), *cert. denied*, 117 S. Ct. 965 (1997).

2. Rule 702 Provides for Broad Discretion.

Rule 702 as well speaks to this issue. Rule 702 allows a qualified witness to offer opinions only "[i]f *scientific*, technical, or other specialized *knowledge* will *assist* the trier of fact." (Emphasis supplied.)

> "[T]he Rules of Evidence—especially Rule 702—do assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand."

Daubert, 509 U.S. at 597. "We are confident that federal judges possess the capacity to undertake this review." *Id.* at 593.

"The *Daubert* Court significantly changed the standards governing the admissibility of scientific evidence by expanding district courts' discretions to evaluate the reliability and relevance of contested evidence." *In re Joint Eastern & Southern Dist. Asbestos Litigation*, 52 F.3d 1124, 1132 (2d Cir. 1995). *Daubert* "shifted to the trial judge the responsibility for keeping 'junk science' out of the courtroom." *Wilson* v. *City of Chicago*, 6 F.3d 1233, 1238 (7th Cir. 1993), *cert. denied*, 511 U.S. 1088 (1994). See also American College of Trial Lawyers, *Standards and Procedures for Determining the Admissibility of Expert Evidence After Daubert*, 157 F.R.D. 571, 571 (1994) ("*Daubert* clearly requires trial judges to subject expert evidence to more penetrating pretrial scrutiny"); Rehnquist, *1993 Year-End Report on the Federal Judiciary*, 17 AM. J. TRIAL ADVOC. 571, 579 (1994) ("the *Daubert* case . . . vested more responsibility in the trial judge for assessing the reliability and relevance of scientific expert testimony").

This Court in *Daubert* several times emphasized that

> "The inquiry envisioned by Rule 702 is, we emphasize, a flexible one."

Id. at 594; see also *id.* at 593, 597. Such flexibility for the trial court's exercise of its assignment, mandated by Rule 702, implies a deferential standard for the appellate tribunal that reviews the trial court's rulings. "[W]e adopted deferential review to afford 'the district court the necessary flexibility to resolve questions involving multifarious, fleeting, special, narrow facts that utterly resist generalization." *Koon* v. *United States*, *supra*, 116 S. Ct. at 2047 (internal quotation marks omitted), quoting *Cooter & Gell* v. *Hartmarx Corp.*, *supra*, 496 U.S. at 404, *Pierce* v. *Underwood*, *supra*, 487 U.S. at 561-62, and Rosenberg, *Judicial Discretion of the Trial Court, Viewed From Above*, 22 SYRACUSE L. REV. 635, 662 (1971). Admissibility rulings commonly "involve 'fact-

intensive, close calls.'" *Cooter & Gell, supra,* 496 U.S. at 404, quoting C. SHAFFER & P. SANDLER, SANCTIONS: RULE 11 AND OTHER POWERS 15 (2d ed. 1988).

B. Appellate Courts Traditionally Have Allowed Broad Discretion to Trial Court Rulings on Admissibility of Expert Testimony.

1. *This Court Has Applied a "Manifestly Erroneous" Standard.*

In determining "the question of what is the standard of appellate review" for trial court determinations, "[f]or most . . . the answer is provided by a long history of appellate practice." *Pierce* v. *Underwood, supra,* 487 U.S. at 558; see also *Miller* v. *Fenton,* 474 U.S. 104, 115 (1985). For more than a century the control of expert testimony—whether the witness is qualified and whether his or her opinions will assist the trier of fact—has been recognized by this Court, as it was at common law, as a matter for trial judges' broad discretion.

> "Whether a witness called to testify to any matter of opinion has such qualifications and knowledge as to make his testimony admissible is a preliminary question for the judge presiding at the trial; and his decision of it is conclusive, unless clearly shown to be erroneous in matter of law."

Stillwell & Bierce Mfg. Co. v. *Phelps,* 130 U.S. 520, 527 (1889).

> "Cases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but *the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous.*"

Spring Co. v. *Edgar,* 99 U.S. 645, 658 (1879) (emphasis supplied). "How much knowledge a witness must possess before a party is entitled to his opinion as an expert is a matter which, in the nature of things, must be left largely to the discretion of the trial court, and its ruling thereon will not be disturbed unless clearly erroneous." *Chateaugay Ore & Iron Co.* v. *Blake,* 144 U.S. 476, 484 (1892). See also, *e.g., Gila Valley, G. & N. Ry.* v. *Hall,* 232 U.S. 94, 103 (1914); *Inland & Seaboard Coasting Co.* v. *Tolson,* 139 U.S. 551, 559 (1891); *Montana Ry.* v. *Warren,* 137 U.S. 348, 353 (1890); *cf. Spiller* v. *Atchison, T. & S.F. Ry.,* 253 U.S. 117, 130 (1920).

That longstanding rule was reiterated in, *e.g., Salem* v. *United States Lines Co.,* 370 U.S. 31 (1962), and *Hamling* v. *United States,* 418 U.S. 87 (1974). "[T]he trial judge has broad discretion in the matter of the admission or exclusion of expert evidence, and his action is to be sustained unless manifestly erroneous." *Salem,* 370 U.S. at 35. "[T]he District Court has wide discretion in its determination to admit and exclude evidence, and this is particularly true in the case of expert testimony." *Hamling,* 418 U.S. at 108. "Petitioners have very much the laboring oar in showing that such rulings constitute reversible error . . . ." *Id.* at 124.

Prior to *Daubert* there was no doubt as to the standard of appellate review of rulings admitting or excluding expert testimony. The standard was expressed either as "manifest error" or "abuse of discretion."[18] There is not a bit of evidence that the drafters of the Federal Rules, this Court, or Congress intended to change it. When a "common-law precept" is "entirely consistent with" a rule's "general requirement," then it is "unlikely that the drafters had intended to change the rule." *Daubert, supra,* 509 U.S. at 588. See also, *e.g., United States* v. *Abel, supra,* 469 U.S. at 50 ("With this state of

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[18] See, *e.g., United States* v. *Butt,* 955 F.2d 77, 85 (1st Cir. 1992); *United States* v. *Cruz,* 981 F.2d 659, 662 (2d Cir. 1992); *United States* v. *Wright-Barker,* 784 F.2d 161, 169 n.6 (3d Cir. 1986); *Friendship Heights Assocs.* v. *Koubek,* 785 F.2d 1154, 1159 (4th Cir. 1986); *Christophersen* v. *Allied-Signal Corp.,* 939 F.2d 1106, 1109 (5th Cir. 1991), *cert. denied,* 503 U.S. 912 (1992); *United States* v. *Price,* 995 F.2d 729, 731 (7th Cir. 1993); *Cashman* v. *Allied Prods. Corp.,* 761 F.2d 1250, 1254 (8th Cir. 1985); *United States* v. *Cuevas,* 847 F.2d 1417, 1429 (9th Cir. 1988), *cert. denied,* 489 U.S. 1012 (1989); *Broadcort Capital Corp.* v. *Summa Med. Corp.,* 972 F.2d 1183, 1194-95 (10th Cir. 1992); *United States* v. *Hall,* 969 F.2d 1102, 1109-10 (D.C. Cir.), *cert. denied,* 506 U.S. 980 (1992); *Milmark Services* v. *United States,* 731 F.2d 855, 860 (Fed. Cir. 1984).

unanimity confronting the drafters of the Federal Rules of Evidence, we think it unlikely that they intended to scuttle entirely the evidentiary availability of cross-examination for bias"); *Tome* v. *United States*, 513 U.S. 150, 160 (1995) (Fed. R. Evid. 801(d)(1)(B) "was intended to carry over the common-law premotive rule"); *United States* v. *Mezzanatto*, 513 U.S. 196, 202 (1995) (interpreting Fed. R. Evid. 410 in light of practice "at the time of the adoption of the Federal Rules of Evidence"); *Green* v. *Bock Laundry Machine Co.*, 490 U.S. 504, 521 (1989); *Midlantic Nat'l Bank* v. *New Jersey Dep't of Envtl. Protection*, 474 U.S. 494, 501 (1986). Indeed, to alter the established standard of review by decision, in the face of such an established body of law, would be inconsistent with the rule-making process prescribed for this Court and the Congress. See 28 U.S.C. §§ 2072-74.

2. *The Federal Courts of Appeals After* Daubert *Have Continued To Apply a Standard Recognizing Broad Discretion.*

Since *Daubert*, nearly all the federal courts of appeals have considered the standard of appellate review again. Overwhelmingly, without difficulty or controversy, they have concluded that there is no basis to alter the familiar standard that allows very broad discretion in admissibility rulings for the trial judge. "In reviewing the district court's fact-specific application of the approach mandated by *Daubert*, we must apply a deferential standard of review." *Deimer* v. *Cincinnati Sub-Zero Prods., Inc.*, 58 F.3d 341, 344 (7th Cir. 1995). "*Daubert* requires district judges to act as gatekeepers to ensure that scientific evidence is both relevant and reliable. . . . Their decisions, therefore, are properly reviewed under the traditional abuse of discretion standard." *Duffee* v. *Murray Ohio Mfg. Co.*, 91 F.3d 1410, 1411 (10th Cir. 1996). Six circuits, in accordance with their own precedents and this Court's decisions, hold that district court rulings applying *Daubert* will be reversed only if "manifestly erroneous."[19] Four other circuits simply describe the standard as "abuse of discretion," often emphasizing the great latitude accorded the trial court.[20] It has been observed that as a practical matter, either formulation may amount to the same thing: a very deferential standard of review, under which "the trial judge's ruling, whether excluding or admitting expert evidence, will not be disturbed, except in rare instances." 4 WEINSTEIN'S FEDERAL EVIDENCE § 702.02[2] (J. McLaughlin 2d ed. 1997).

Respondents themselves, in opposing certiorari and urging that the present decision should be ignored, argued to this Court that "all circuits . . . apply the same standard when reviewing a district court's decision on the admission of expert testimony, using the description of 'abuse of discretion' and 'manifestly erroneous' interchangeably—indeed, often together." Br. Opp. 9-10. "[A]ll circuits

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[19] *E.g.*, *United States* v. *Sepulveda*, 15 F.3d 1161, 1183 (1st Cir. 1993), *cert. denied*, 512 U.S. 1223 (1994); *United States* v. *Daccarett*, 6 F.3d 37, 58 (2d Cir. 1993), *cert. denied*, 510 U.S. 1192, *and* 511 U.S. 1030 (1994); *United States* v. *14.38 Acres*, 80 F.3d 1074, 1077 (5th Cir. 1996); *American & Foreign Ins. Co.* v. *General Elec. Co.* 45 F.3d 135, 137 (6th Cir. 1995); *Bradley* v. *Brown*, 42 F.3d 434, 436-37 (7th Cir. 1994); *Claar* v. *Burlington N.R.R.*, 29 F.3d 499, 500-01 (9th Cir. 1994). For other examples see Pet. Cert. 7-9.

[20] *E.g.*, *United States* v. *Dorsey*, 45 F.3d 809, 813-14 (4th Cir.), *cert. denied*, 115 S. Ct. 2631 (1995); *Gier* v. *Educational Service Unit*, 66 F.3d 940, 944 (8th Cir. 1995); *Duffee* v. *Murray Ohio Mfg. Co.*, 91 F.3d 1410, 1411 (10th Cir. 1996). The District of Columbia Circuit likewise has held that review of Rule 702 rulings should accord trial judges "broad discretion," *Joy* v. *Bell Helicopter Textron, Inc.*, 999 F.2d 549, 567 (D.C. Cir. 1993), and that when expert testimony is excluded "[w]e review the district court's judgment for abuse of discretion." *Raynor* v. *Merrell Pharmaceuticals, Inc.*, 104 F.3d 1371, 1374 (D.C. Cir. 1997). For other examples see Pet. Cert. 9-11. An earlier 2-1 opinion of a panel of the D.C. Circuit, prior to *Raynor*, appeared to treat exclusion of expert testimony leading to summary judgment as a matter for *de novo* review; rehearing *en banc* was denied by a vote of 5-5. *Ambrosini* v. *Labarraque*, 101 F.3d 129, 132 (D.C. Cir. 1996), *pet'n for cert. dismissed sub nom. Upjohn Co.* v. *Ambrosini*, 65 U.S.L.W. 3755 (U.S. 1997) (No. 96-1552).

employ the 'abuse of discretion' standard for review of district court decisions regarding expert testimony, sometimes referring to it using the older, 'manifestly erroneous' language." *Id.* at 13. "[A]ll circuits are in broad agreement. The 'abuse of discretion' standard, sometimes called the 'manifestly erroneous' standard applies everywhere . . . ." *Id.* at 15.

3. *State Courts Have Interpreted Both Common Law and State Versions of Rule 702 To Allow Great Discretion.*

"It is well established that the body of common law knowledge must be a source of guidance in our interpretation of the rules." *Tome* v. *United States*, 513 U.S. 150, 168 (1995) (Scalia, J., concurring) (internal quotation marks omitted), quoting *Daubert*, 509 U.S. at 588, *United States* v. *Abel*, *supra*, 469 U.S. at 52, and Cleary, *Preliminary Notes on Reading the Rules of Evidence*, 57 NEB. L. REV. 908, 915 (1978). The standard of review at common law for rulings on admissibility of expert testimony spans at least two centuries. See, *e.g.*, *Sorg* v. *First German Evangelical St. Paul's Congregation*, 63 Pa. 156, 161-62 (1869):

> "[W]e will not reverse either on account of admission or rejection of such evidence, unless in a clear and strong case . . . . It lies within the limits of discretion."

People v. *Mooney*, 76 N.Y.2d 827, 828, 559 N.E.2d 1274, 1274 (1990):

> "Here, the trial court based its decision to exclude the [expert] testimony in the exercise of its sound discretion to which the admission of such evidence would, if legally admissible at all, be entrusted. Our review powers are limited accordingly . . . ." [21]

[21] *Accord, e.g., Traver* v. *Spokane Street Ry.*, 25 Wash. 225, 254, 65 Pac. 284, 294 (1901); *Fair Mercantile Co.* v. *St. Paul Fire & Marine Ins. Co.*, 237 Mo. App. 511, 523, 175 S.W.2d 930, 937 (1943); *State* v. *Kemp*, 199 Conn. 473, 476, 507 A.2d 1387, 1388-89 (1986); *People* v. *Roberts*, 2 Cal. 4th 271, 298, 826 P.2d 274, 286, *cert. denied*, 506 U.S. 964 (1992).

Since the enactment of the Federal Rules of Evidence in 1975, many states have adopted provisions identical to Rules 104(a) and 702 or nearly so. Overwhelmingly, in applying those rules, state courts have held that exclusions of scientific evidence are reviewed for abuse of discretion or manifest error. *E.g.*, *State* v. *Dirk*, 364 N.W.2d 117, 120 (S.D. 1985):

> "[W]e adopted the same standard of review with respect to our rule that the federal courts have applied to Rule 702. Under this standard, the trial court has broad discretion in determining the qualifications of expert witnesses and in admitting expert testimony. The trial court's decisions in this regard will not be reversed in the absence of a clear showing of an abuse of that discretion." [22]

[22] See also, *e.g.*, *Shepard* v. *State*, 847 P.2d 75, 79 (Alaska App. 1993) ("trial court's decision excluding expert testimony [under Alaska R. Evid. 702] is subject to reversal for abuse of discretion"); *State* v. *Mincey*, 141 Ariz. 425, 441, 687 P.2d 1180, 1196 (under Ariz. R. Evid. 702 "[t]he determination of whether an expert's opinion will so help the jury is a matter within the sound discretion of the trial court"), *cert. denied*, 469 U.S. 1040 (1984); *Wade* v. *Grace*, 321 Ark. 482, 486, 902 S.W.2d 785, 788 (1995) (under Ark. R. Evid. 702 "[w]hether a witness may give expert testimony rests largely within the sound discretion of the trial court, and that determination will not be reversed absent an abuse of discretion"); *People* v. *Jones*, 743 P.2d 44, 48 (Colo. App. 1987) ("[t]he trial court has broad discretion in ruling on the admissibility of expert witness testimony under CRE 702, and its determination whether such evidence will assist the jury will not be disturbed on appeal absent abuse of that discretion"); *Craft* v. *Peebles*, 78 Haw. 287, 301, 893 P.2d 138, 152 (1995) ("[o]n appeal the admissibility of expert testimony [under Haw. R. Evid. 702] is reviewed for abuse of discretion"); *Cook* v. *City of Detroit*, 125 Mich. App. 724, 735, 337 N.W.2d 277, 282 (1983) ("The decision of the trial court [under Mich. R. Evid. 702] will not be reversed absent an abuse of that discretion"); *Bowman* v. *McDonald's Corp.*, 916 S.W.2d 270, 282 (Mo. App. 1995) (under Mo. Rev. Stat. § 490.065 "[a] trial court does not usually commit reversible error by mere exclusion of expert testimony"); *Cottrell* v. *Burlington N.R.R.*, 261 Mont. 296, 301, 863 P.2d 381, 384 (1993) ("the determination of the qualification and competency of expert witnesses [under Mont. R. Evid. 702] rests largely within the trial judge, and without a showing of an abuse of discretion, such deter-

And those states that under such rules have specifically endorsed the analysis of *Daubert* have also adopted a deferential standard of appellate review. *E.g.*, *Steward* v.

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mination will not be disturbed"); *State* v. *Case*, 4 Neb. App. 885, 902, 553 N.W.2d 173, 184 (1996) ("The trial court's determination of whether an expert's opinion testimony will be helpful to the jury or assist the trier of fact in accordance with [Neb. R. Evid. 702] is a determination involving the discretion of the trial court, whose ruling on the admissibility will be upheld on appeal unless the trial court abused its discretion"); *State* v. *Girmay*, 139 N.H. 292, 294, 652 A.2d 150, 151-52 (1994) (review of exclusion under N.H.R. Evid. 702 is for abuse of discretion); *State* v. *Long*, 119 N.J. 439, 495, 575 A.2d 435, 463 (1990) ("[w]e find no abuse of discretion in the court's exclusion of Dr. Buckhout's testimony" under N.J.R. Evid. 702); *Smith* v. *Pass*, 95 N.C. App. 243, 251, 382 S.E.2d 781, 786 (1989) (under N.C.R. Evid. 702, the trial "judge is given wide latitude of discretion when making a determination about the admissibility of expert testimony. . . . A determination of whether the opinion evidence is sufficiently reliable and relevant is also within the judge's discretion"); *Larsen* v. *Zarrett*, 498 N.W.2d 191, 195 n.2 (N.D. 1993) ("the decision to admit or not to admit expert testimony under Rule 702, N.D. R. Ev., rests within the sound discretion of the trial court, and its decision will not be reversed on appeal unless the court has abused its discretion); *State* v. *Awkal*, 76 Ohio St. 3d 324, 331, 667 N.E.2d 960, 968 (1996) (under Ohio R. Evid. 702 "all questions concerning the admission or exclusion of this kind of evidence are considered on an abuse of discretion basis"), *cert. denied*, 117 S. Ct. 776 (1997); *State* v. *Griffin*, 691 A.2d 556, 557 (R.I. 1997) ("Trial justices have wide discretion" as "evidentiary gatekeepers" under R.I. R. Evid. 702); *State* v. *Dirk*, *supra* (S.D. Cod. L. § 19-15-2, Rule 702); *State* v. *Campbell*, 904 S.W.2d 608, 615 (Tenn. Cr. App. 1995) ("this Court will not interfere . . . unless it appears on the face of the record that the trial court abused its discretion"); *Soutiere* v. *Soutiere*, 163 Vt. 265, 269, 657 A.2d 206, 208 (1995) (under Vt. R. Evid. 702, "[t]rial courts have wide discretion in making evidentiary rulings, and we will not overturn the court's decision in the absence of an abuse of discretion"); *State* v. *Kalakosky*, 121 Wash. 2d 525, 541, 852 P.2d 1064, 1072-73 (1993) ("standard of review whereby the appellate court accords deference to the discretion of the trial court" in ruling under Wash. R. Evid. 702); *Hatch* v. *State Farm Fire & Cas. Co.*, 930 P.2d 382, 388 (Wyo. 1997) ("it is not the purpose of Wyo. R. Evid. 702 to provide blanket admissibility of expert testimony, but instead, to vest the trial court with the discretion to determine whether to exclude

State, 652 N.E.2d 490, 498-99 (Ind. 1995); *Mitchell* v. *Commonwealth*, 908 S.W.2d 100, 102 (Ky. 1995); *E.I. du Pont de Nemours & Co.* v. *Robinson*, 923 S.W.2d 549, 558 (Tex. 1995); *State* v. *Anderson*, 118 N.M. 284, 291, 881 P.2d 29, 37 (1994). *But see Gentry* v. *Mangum*, 195 W. Va. 512, 519, 466 S.E.2d 171, 178 (1995), *infra* n.23.

4. *The "Particularly Stringent" Standard Is a Recent Invention That Has Been Widely Rejected.*

The Court of Appeals relied as authority for its "particularly stringent" standard of review on a 1994 decision of the Third Circuit, *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994), *cert. denied sub nom. General Electric Co.* v. *Ingram*, 115 S. Ct. 1523 (1995). P.C.A. 5a. The *Paoli* opinion announced that

> "While evidentiary rulings are generally subject to a particularly high level of deference because the trial court has a superior vantage point to assess the evidence, . . . evaluating the reliability of scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses and thus is often not significantly more difficult on a cold record.

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testimony demed unnecessary or not helpful to the trier of fact"). See also *Cunningham* v. *McDonald*, 689 A.2d 1190, 1193-94 (Del. 1997); *Chambliss* v. *White Motor Corp.*, 481 So. 2d 6, 8 (Fla. App. 1985), *rev. denied*, 491 So. 2d 278 (Fla. 1986); *State* v. *Schneider*, 129 Idaho 59, 921 P.2d 759, 762 (Idaho App. 1996); *State* v. *Small*, 1997 WL 175079, at *17-18 (La. App. 1997); *State* v. *Boobar*, 637 A.2d 1162, 1167 (Me. 1994); *Emmons* v. *State*, 107 Nev. 53, 56, 807 P.2d 718, 720 (1991); *Drake* v. *Wal-Mart, Inc.*, 876 P.2d 738, 742 (Okla. App. 1994); *State* v. *Wilson*, 121 Or. App. 460, 464, 855 P.2d 657, 659, *rev. denied*, 318 Or. 61, 865 P.2d 1297 (1993); *Walker* v. *Bluffs Apartments*, 477 S.E.2d 472, 473 (S.C. App. 1996); *Kent* v. *Pioneer Valley Hospital*, 930 P.2d 904, 906 (Utah App. 1997); *State* v. *Ross*, 203 Wis. 2d 66, 80, 552 N.W.2d 428, 433-34 (Wis. App. 1996). *Cf. State* v. *Borchardt*, 478 N.W.2d 757, 760 (Minn. 1991) (under Minn. R. Evid 702, "[t]he decision of whether to admit expert opinion testimony is within the trial court's discretion, and a reviewing court will not reverse unless there is an 'apparent error'").

> Moreover, here there are factors that counsel in favor of a hard look at (more stringent review of) the district court's exercise of discretion. For example, because the reliability standard of Rules 702 and 703 is somewhat amorphous, there is a significant risk that district judges will set the threshold too high and will in fact force plaintiffs to prove their case twice. Reducing this risk is particularly important because the Federal Rules of Evidence display a preference for admissibility."

35 F.3d at 749-50 (emphasis in original). Citing "preference for admissibility," the *Paoli* opinion held that

> "the likelihood of finding an abuse of discretion is affected by the importance of the district court's decision to the outcome of the case and the effect it will have on important rights."

Id. at 750.

> "We acknowledge that there is arguably a tension between the substantial deference normally accorded to rulings where the trial court has a superior vantage point and the preference for admissibility of the Federal Rules of Evidence. We resolve any such tension by holding that *when the district court's exclusionary rulings with respect to scientific opinion testimony will result in a summary or directed judgment, we will give them a 'hard look' (more stringent review, . . .)* to determine if a district court has abused its discretion in excluding evidence as unreliable."

Id. (footnote omitted; emphasis supplied). For its newly announced standard the *Paoli* opinion relied in part upon *United States* v. *Pennsylvania, Dep't of Envtl. Resources*, 923 F.2d 1071, 1073 (3d Cir. 1991), which had held that appellate review of district-court decisions declining to hear declaratory judgment cases should be more demanding because "the Declaratory Judgment Act [28 U.S.C. § 2201] should 'have a liberal interpretation;'" a year later the reasoning of that case was disapproved by this Court's decision in *Wilton* v. *Seven Falls Co., supra*, 115 S. Ct. at 2143-44 (holding proper standard of review was abuse-of-discretion).

Although in the present case the Eleventh Circuit simply adopted *Paoli*'s selective "hard look" "more stringent" standard of review without further discussion, all other courts of appeals that have taken note of the *Paoli* standard have specifically rejected it. In *Duffee* v. *Murray Ohio Mfg. Co.*, 91 F.3d 1410 (10th Cir. 1996), the Tenth Circuit, after acknowledging both the present case and *Paoli*, explained that

> "Like the Supreme Court, we 'are confident that federal judges possess the capacity to undertake this [*Daubert*] review.' . . . Their decisions, therefore, are properly reviewed under the traditional abuse of discretion standard."

91 F.3d at 1411, quoting *Daubert*, 509 U.S. at 593. The Fourth Circuit also declined to adopt the *Paoli* standard. *Cavallo* v. *Star Enterprise*, 100 F.3d 1150, 1153 (4th Cir. 1996), *pet'n for cert. filed*, 65 U.S.L.W. 3666 (U.S. 1997) (No. 96-1493); see also *Lust* v. *Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 597 (9th Cir. 1996). The *Paoli* opinion's "creation of a new and higher standard of review" was criticized by one federal judge as "without authority or precedent." Wiseman, *Judging the Expert*, 55 OHIO ST. L.J. 1105, 1112 (1994). Before the present decision, it had been observed that

> "*Paoli* stands almost alone—alone but for later cases in its circuit that pick up its language—in expressing the standard of review as anything but the most lenient kind of review for abuse of discretion. The non-*Paoli* cases seem to be correct."

Fenner, *The Daubert Handbook: The Case, Its Essential Dilemma, and Its Progeny*, 29 CREIGHTON L. REV. 939, 1030 (1996) (footnote omitted).[23]

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[23] A single state-court opinion has cited the *Paoli* view with approval. See *Gentry* v. *Mangum*, 195 W. Va. 512, 519, 466 S.E.2d 171, 178-79 (1995) (reviewing Rule 702 exclusion under summary-judgment standard, but stating that exclusions under Rules 403 or 703 would be reviewed for abuse of discretion). *But cf. State* v. *LaRock*, 196 W. Va. 294, 306-07, 470 S.E.2d 613, 625-26 (1996) (in applying Rule 702 "appellate courts give trial judges a wide berth of respect with regards to these kinds of discretionary judgments,"

Moreover, as this Court in *Daubert* pointed out, 509 U.S. at 595, Rule 403 of the Federal Rules of Evidence often will overlap Rule 702. Rule 403 authorizes trial courts to exclude testimony, even if otherwise admissible, "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." It would serve little practical purpose to subject trial judges to a "particularly stringent" standard of appellate review of exclusions under Rule 702, when similar considerations often would also support exclusion under Rule 403. Rule 403 confers "wide discretion" and invokes "the district court's sound judgment;" exclusions under Rule 403 are reversed on appeal only for abuse of discretion. *United States* v. *Abel, supra,* 469 U.S. at 54; see also *Old Chief* v. *United States,* 117 S. Ct. 644, 650 (1997). To impose a "particularly stringent" review standard for Rule 702 exclusions—which usually are accompanied by an articulated application of criteria outlined in *Daubert*—could simply invite invocation instead of the more general discretion of Rule 403.[24]

Also, as *Daubert* further pointed out, 509 U.S. at 595, Fed. R. Evid. 703 (which requires facts or data to be "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject") is sometimes yet another basis for exclusion. The trial court here could have applied Rule 703 to exclude opinions based on the two mouse studies, in light of the testimony of even Dr. Teitelbaum that scientists do not decide human carcinogenicity from such animal studies. J.A. 158, 160, 170; *accord*, J.A. 265, 267-68, 270. The standard of appellate review for Rule 703

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review "only for abuse of discretion," and "there is no principled way for us to second guess that ruling") (exclusion of defendant's expert; criminal conviction).

[24] See FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 117 (1994) ("If courts adopt stringent standards [under Rules 702 and 703], then trial courts may tend to bolster their conclusions with a Rule 403 analysis that will be governed by an abuse-of-discretion standard of review").

exclusions is well established to be abuse-of-discretion. *E.g., Cummins* v. *Lyle Indus.*, 93 F.3d 362, 371 (7th Cir. 1996); *Christophersen* v. *Allied-Signal Corp.*, 939 F.2d 1106, 1115 (5th Cir. 1991) (*en banc*), *cert. denied*, 503 U.S. 912 (1992); *United States* v. *Wilson*, 798 F.2d 509, 517 (1st Cir. 1986); 3 J. WEINSTEIN *et al.*, WEINSTEIN'S EVIDENCE § 703[01] (1996).

C. Functional Criteria Confirm a Deferential Standard of Review.

When, unlike here, no standard is apparent from statute, rule, or established practice, this Court has identified criteria for determining the proper standard of appellate review: functional considerations such as which court, trial or appellate, is better situated to assess such an issue; whether the decisions will most often be fact-bound; and whether the time taken by an appellate court to retrace in detail a district court's effort is likely to produce a more reliable result or to provide doctrinal guidance useful for future cases. Here all those criteria reinforce the commitment of the Rules themselves to wide discretion for the trial court.

1. *District Courts Are Better Situated To Make Admissibility Determinations.*

"[T]he reviewing attitude that a court of appeals takes toward a district court decision should depend upon 'the respective institutional advantages of trial and appellate courts' . . . ." *First Options of Chicago, Inc.* v. *Kaplan*, 115 S. Ct. 1920, 1926 (1995), quoting *Salve Regina College* v. *Russell*, 499 U.S. 225, 233 (1991). "[D]eference [is] owed to the judicial actor . . . better positioned than another to decide the issue in question." *Koon* v. *United States, supra*, 116 S. Ct. at 2047 (internal quotation marks omitted), quoting *Pierce* v. *Underwood, supra*, 487 U.S. at 559-60, and *Miller* v. *Fenton*, 474 U.S. 104, 114 (1985). *Accord, Wilton* v. *Seven Falls Co., supra*, 115 S. Ct. at 2144. Fact-oriented and case-specific determinations are "[t]he trial judge's major role," and "with experience in fulfilling that role comes expertise." *Icicle Seafoods, Inc.* v. *Worthington*, 475 U.S. 709, 714

(1986), quoting *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574 (1985).[25]

Daubert explained that with respect to reliability,

> "Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test."

509 U.S. at 593. It enumerated as examples testability, peer review, publication, error rate, existence of standards, and degree of acceptance in the relevant scientific community. *Id.* at 593-94. Those are considerations pointing to particular facts, not legal research. Likewise, Rule 702's requirement of relevance or "fit" considers "whether expert testimony proffered in the case is sufficiently tied to the facts of the case." 509 U.S. at 591, quoting *United States* v. *Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985).

District courts are particularly adapted to handle issues that involve "multifarious" considerations that are "little susceptible . . . of useful generalization." *Pierce* v. *Underwood*, 487 U.S. 552, 562 (1988). They are also "better situated than the court of appeals" to apply a "fact-dependent legal standard." *Cooter & Gell* v. *Hartmarx Corp.*, *supra*, 496 U.S. at 402; see also *Denton* v. *Hernandez*, 504 U.S. 25, 33 (1992) ("district courts . . . are all too familiar with factually frivolous claims"); *Hensley* v. *Eckerhart*, 461 U.S. 424, 437 (1983) ("the desirability of avoiding frequent appellate review of what essentially are factual matters"); *Curtiss-Wright Corp.* v. *General Elec. Co.*, 446 U.S. 1, 10-11 (1980) ("because the number of possible situations is large, we are reluctant either to fix or sanction narrow guidelines for the district courts to follow") (discretionary certifications under Fed. R. Civ. P. 54(b)). "[W]hether information will 'assist' [Rule 702] or 'confuse' [Rule 403] the trier of fact is a quintessential judicial judgment call."

[25] *Cf. Ornelas* v. *United States*, 116 S. Ct. 1657, 1663 (1996) (emphasizing that even though rule of independent review of Fourth Amendment probable-cause determinations is long established, "we hasten to point out that a reviewing court should take care" to review factfindings only for clear error "and to give due weight to inferences drawn from those facts by resident judges").

Becker & Orenstein, *The Federal Rules of Evidence After Sixteen Years*, 60 G. WASH. L. REV. 857, 868 (1992) (footnotes omitted; brackets in original).[26]

2. *"Particularly Stringent" Appellate Review Would Consume Additional Resources Without Demonstrably Improving Results.*

There is no basis to assume that courts of appeals, removed as they are from the conduct and factual details of a case, would be likely somehow to reach more accurate or sound results in applying the "reliability" and "helpfulness" tests of Rule 702. The present case is a good illustration. In several instances, the Court of Appeals not only engaged in unauthorized appellate factfinding.[27] In doing so, it also misunderstood the record:

—It believed, for example, that "each opinion proffered by the Joiners' experts as scientific knowledge was supported by . . . physical examination of Joiner." P.C.A. 8a. In fact, Dr. Schecter concededly had never examined him at all, and only once had even spoken to him, J.A. 103-05—in a lawyer's office, "to get a feel for what kind of person he was, whether he was a person I would find believable." J.A. 103. Indeed, Dr. Schecter acknowledged that "if this isn't settled in a reasonable fashion

[26] Nor does appellate deference to admissibility rulings depend on a trial court's having followed a particular procedure; as with many preliminary determinations, Rule 104(a) does not specify any. See *Huddleston* v. *United States*, 485 U.S. 681, 689-90 (1988); *cf. Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574 (1985) (deferential "clear error" standard for factfindings under Fed. R. Civ. P. 52(a) applies "even when the district court's findings do not rest on credibility determinations, but are based instead on physical or documentary evidence").

[27] See *Pullman-Standard* v. *Swint*, 456 U.S. 273, 293 (1982) ("incredible" not to remand to district court if rule of law had been applied incorrectly); *Icicle Seafoods, Inc.* v. *Worthington*, *supra*, 475 U.S. at 714 ("the Court of Appeals was mistaken to engage in . . . factfinding"). Respondent told the Court of Appeals that "in determining whether a plaintiff's experts have used a valid methodology in reaching their conclusions, a district court must make a *factual* determination . . . ." Reply Brief of Plaintiffs-Appellants, No. 94-9131, 11th Cir., at 7 (emphasis in original).

and goes to trial, then one might want to be a little more thorough with Mr. Joiner." J.A. 108. Dr. Teitelbaum also had talked with respondent only once, also at the lawyers' office; without details he described what he did to be "as complete an examination as one could do not working in one's own office." J.A. 137-38, 139.[28] Neither expert ordered any tests or communicated with the treating physicians. J.A. 103-04, 138, 139.

—Although the Court of Appeals emphasized that "[i]n arriving at his opinion, Schecter claimed to have eliminated other potential causes of Joiner's lung cancer to a reasonable degree of medical certainty," P.C.A. 10a, the Court of Appeals appeared unaware that in his deposition Dr. Schecter had conceded that "[m]ost lung cancer in the United States is caused by cigarette smoking," J.A. 109, and "I believe more likely than not that Mr. Joiner's lung cancer was causally linked to cigarette smoking and PCB exposure," J.A. 107.

—In accepting the assumptions of the two physicians that dioxins or furans could be formed at some temperature from PCBs, the Court of Appeals ignored that Dr. Schecter and Dr. Teitelbaum each had conceded lack of expertise in physical chemistry. J.A. 109, 156-57. Indeed, Dr. Teitelbaum, when asked if he had that competence, exclaimed "Heavens, no." J.A. 157. Neither was able to state with certainty at what temperature they thought such a conversion might occur. J.A. 122-23, 156-57.

—The Court of Appeals then concluded that "[t]he defendants never succeeded in rebutting the conclusions of the Joiners' experts by either establishing a threshold temperature . . . or presenting any direct evidence of the actual temperatures." P.C.A. 15a. But, even assuming such a burden rested on petitioners (*but see* p. 45, *infra*),

[28] *Cf. Land* v. *United States*, 35 Fed. Cl. 345, 352 n.7 (1996) (holding that Dr. Teitelbaum's " 'preliminary' medical opinion that plaintiffs' injuries were probably caused by DIMP poisoning is of little value because Dr. Teitelbaum did not conduct physical examinations of the plaintiffs"), *aff'd*, 37 Fed. Cl. 231 (1997).

the record contained expert testimony of two chemists that even undiluted PCBs do not form dioxins under any conditions, J.A. 367, 370, and pure PCBs convert to furans if at all only under prolonged temperatures of at least 300° C., J.A. 362, 372. The record also showed that the paper insulation of the transformers would char or burn well below 300° C., J.A. 366, so that transformers should not be dried at temperatures above 85° to 90° C. J.A. 506, 507.[29]

—The Court of Appeals described Dr. Teitelbaum as "a practicing toxicologist" who "has repeated experience *treating* patients from the electrical trades." P.C.A. 8a n.8 (emphasis supplied). According to the record, however, Dr. Teitelbaum was a practicing witness. See J.A. 175-83 (listing 347 litigation appearances); see also J.A. 184-85 (bill for litigation services). What he testified was that he spent a minority of his time on unspecified "patient care," J.A. 169, and that he had "interviewed" and "seen" electrical workers, J.A. 141, with whom he had "experience." J.A. 450. His contact with them, as he elsewhere described it, J.A. 167, was that

> "Usually I see the people who are sick, and usually if I feel that the causation is what I think it is and I write that in a report and somebody comes to me and says, 'Will you testify about that?' I will say yes."

—Quite unaccountably the Court of Appeals stated that "defendants do not challenge" the assertion that Drs. Schecter's and Teitelbaum's opinions rested on accepted

[29] The Court of Appeals unquestioningly adopted Dr. Teitelbaum's surmise that "['Joiner] says it was hot enough for it to smoke, and oil smokes at around 700 degrees, 800 degrees [centigrade].' " P.C.A. 16a; see J.A. 156. The record contained uncontroverted data, however, that mineral oil produces ignitable vapor (flash point) at about 150° C. or less. J.A. 362, 504. A temperature of 700° C., which Dr. Teitelbaum assumed could be produced by large light bulbs, would exceed the melting points of many metals. See CRC HANDBOOK OF CHEMISTRY AND PHYSICS 12-159 to 12-160 (D. Lide 75th ed. 1994) (lead, 327° C.; zinc, 420° C.; magnesium, 650° C.; aluminum, 660° C.). As was noted by the dissenting judge, P.C.A. 23a, respondents never attempted to rely on that statement by Dr. Teitelbaum, but the Court of Appeals did.

methodology. P.C.A. 11a. On the contrary, petitioners repeatedly and explicitly had challenged the opinions for failure to follow scientific methodology; petitioners did so through other expert witnesses, *e.g.*, J.A. 232-33, 234-37, 265, 279, 372-73, 379, pp. 10-11, *supra*; in argument, *e.g.*, J.A. 387-88, 390-91; and on appeal, *e.g.*, J.A. 517 ("A methodology which generates opinions based upon inapposite scientific literature is flawed"); J.A. 515 ("The District Court . . . held the plaintiffs' experts' *methodology* inadequate, because there was no scientific link between the cited studies and the proffered opinions".) (emphasis in original).

This case confirms this Court's observation in *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574-75 (1985), that "[d]uplication of the trial judge's efforts in the court of appeals would very likely contribute only negligibly to the accuracy of fact determination at a huge cost in diversion of judicial resources." And "even where the district judge's full knowledge of the factual setting can be acquired by the appellate court, that acquisition will often come at unusual expense . . . ." *Pierce* v. *Underwood*, *supra*, 487 U.S. at 560; see also *Icicle Seafoods, Inc.* v. *Worthington*, *supra*, 475 U.S. at 714.

3. *"Particularly Stringent" Appellate Review of Fact-Intensive Rulings Would Contribute Little to Clarifying Legal Doctrine.*

"[A]ppellate review serves a dual purpose: the correction of legal error and the establishment of legal rules for future guidance." *Church of Scientology* v. *IRS*, 792 F.2d 153, 155 n.1 (D.C. Cir. 1986) (*en banc*) (Scalia, J.), *aff'd*, 484 U.S. 9 (1987). The function of appellate judges is "to devote their primary attention to legal issues." *Salve Regina College* v. *Russell*, *supra*, 499 U.S. at 232.

That function is not likely to be served by having panels of circuit judges apply themselves to "particularly stringent" review of selected district-court admissibility rulings under *Daubert*. "*Daubert*'s mandate . . . requires judges to determine whether proffered testimony somehow merits the label of 'scientifically valid' *at one specific point in time* and in the context of *one specific case*." K. FOSTER & P. HUBER, JUDGING SCIENCE 241 (1997) (emphasis supplied). A court of appeals' occasional conclusion, after parsing an extensive record, that particular experts' opinions were sufficiently reliable as science after all, and on some reading could fit the facts of the particular case, would seldom announce or clarify principles to guide other courts. Rather, a court of appeals in each new case would simply have to go through a new specific record again, applying the established *Daubert* criteria and occasionally second-guessing the district court. "Particularly stringent" review of Rule 702 rulings, which involve "consideration of unique factors that are little susceptible . . . of useful generalization," is "unlikely to establish clear guidelines for lower courts." *Koon* v. *United States*, *supra*, 116 S. Ct. at 2047 (internal quotation marks omitted), quoting *Cooter & Gell* v. *Hartmarx Corp.*, *supra*, 496 U.S. at 404, 405. It would not serve "the law declaration aspect of independent review." *Thompson* v. *Keohane*, 116 S. Ct. 457, 467 (1995).

Nor would that kind of review be a wise allocation of the limited time of courts of appeals, which, if they devote more hours and days to such particularized review activities, will of necessity have less time for the deliberation, study, and explication to which they are particularly suited.

> "The courts of appeals in recent decades have seen an increase in their caseloads disproportionate to caseload increases in the district courts. Changes in standards of review . . . have . . . been identified as [among] potential explanations for this disproportionate rise."

J. MCKENNA, STRUCTURAL AND OTHER ALTERNATIVES FOR THE FEDERAL COURTS OF APPEALS 23 (Fed. Judicial Center 1993). The federal appellate system has been compared to a city in the arid West that needs to conserve its water resources, rather than construct new subdivisions. Rehnquist, *Address to American Bar Ass'n*, Feb. 6, 1989, reprinted in MANHATTAN LAWYER 16 (Feb. 14, 1989); see also Rehnquist, *1993 Year-End Report on the Federal Judiciary*, 17 AM. J. TRIAL ADVOC. 571, 575 (1994) (noting disproportionate increase in ap-

peals); MCKENNA, *supra*, at 42-45 (courts of appeals by 1993 were hearing argument in fewer than half of cases decided on the merits, and issuing opinions in less than one-third). To burden the courts of appeals with more demanding review responsibilities might well result in fewer or less fully considered opinions generally, which would not serve the law at all.

II. AN ASYMMETRICAL "PARTICULARLY STRINGENT" STANDARD OF REVIEW WOULD VIOLATE ACCEPTED DOCTRINE, THE CIVIL RULES, AND *DAUBERT*.

A. This Court Has Consistently Declined Proposals for Double Standards of Review.

Two years ago this Court reiterated that "it is undesirable to make the law more complicated by proliferating review standards without good reasons." *First Options of Chicago, Inc.* v. *Kaplan*, *supra*, 115 S. Ct. at 1926. Yet that is exactly what the Court of Appeals did here. It also made the standard of appellate review turn, not on the nature of the issue on appeal, but rather on how the district court decided it.

That admissibility determinations in scientific-evidence cases may alter outcomes does not set such cases apart from other litigation. Lawyers well know that evidentiary rulings often shape a trial and sometimes are outcome-determinative. Nevertheless, as *Daubert* recognized, Rule 104(a) assigns trial judges great discretion to make preliminary evidentiary rulings, including important ones. It is well recognized that

> "[T]he Trial Judge who excludes the evidence for insufficient proof of the preliminary fact will often preempt the jury. But this is not particularly troublesome. The law of evidence is based on the assumption that a litigant will not get to the jury unless she has enough evidence which the Trial Judge finds to be admissible."

1 S. SALTZBURG *et al.*, FEDERAL RULES OF EVIDENCE MANUAL 60 (6th ed. 1994). Moreover, the consequences of *not* excluding unsupported opinions can be very serious, too. Respondent here was asking, based on these two opinions, not just that petitioners be forced to incur litigation costs, but that they be ordered to pay him tens of millions of dollars.

In many situations this Court has applied abuse-of-discretion review to many kinds of rulings that may have a significant effect on the outcome of a case or even determine it. See, *e.g.*, *Wilton* v. *Seven Falls Co.*, *supra*, 115 S. Ct. at 2143-44 (declining of declaratory-judgment jurisdiction); *Denton* v. *Hernandez*, 504 U.S. 25, 33 (1992) (dismissal of frivolous claim); *Piper Aircraft Co.* v. *Reyno*, 454 U.S. 235, 257 (1981) (dismissal for *forum non conveniens*); *National Hockey League* v. *Metropolitan Hockey Club, Inc.*, 427 U.S. 639, 642 (1976) (dismissal as discovery sanction); see also *Gulf Oil Co.* v. *Bernard*, 452 U.S. 89, 103 (1981) (abuse-of-discretion standard for review of class-certification order under Fed. R. Civ. P. 23(d)); *Curtiss-Wright Corp.* v. *General Elec. Co.*, *supra*, 446 U.S. at 10-11 (abuse-of-discretion standard for certification under Fed. R. Civ. P. 54(b)); *Pierce* v. *Underwood*, *supra*, 487 U.S. at 558 n.1 (collecting cases).[30]

This Court has rejected, in particular, proposals that standards of review should be more deferential or less

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[30] See also *Zafiro* v. *United States*, 506 U.S. 534, 538-39 (1993) (motion for severance); *McFarland* v. *Scott*, 512 U.S. 849, 858 (1994) (capital defendant's motion for stay of execution); *Foman* v. *Davis*, 371 U.S. 178, 182 (1962) (motion to amend complaint). In declining to depart from the abuse-of-discretion standard in reviewing a fee award 1,000 percent of the median, under a statute that had been applied for less than a decade, this Court declined to exclude the possibility of situations in which more intensive review might become appropriate. *Pierce* v. *Underwood*, *supra*, 487 U.S. at 563. The rule this Court adhered to and applied in *Pierce*, however, was stated in upholding *per curiam* a district court's dismissal as a discovery sanction in *National Hockey League* v. *Metropolitan Hockey Club, Inc.*, *supra*: this Court held that courts of appeals must resist the "natural tendency on the part of reviewing courts, . . . to be heavily influenced by the severity of outright dismissal." 427 U.S. at 642. See also *First Options of Chicago*, *supra*, 115 S. Ct. at 1926.

so depending on which way a district court has ruled—that in effect there should be a thumb on the scales of justice favoring a particular outcome.

> "[T]he reviewing attitude that a court of appeals takes toward a district court decision should depend upon 'the respective institutional advantages of trial and appellate courts,' not upon what standard of review will more likely produce a particular substantive result."

First Options of Chicago, Inc. v. *Kaplan, supra*, 115 S. Ct. at 1926, quoting *Salve Regina College* v. *Russell, supra*, 499 U.S. at 231-33. A glaring anomaly of the Court of Appeals' standard would be that on appeal the very same testimony could be held to satisfy or not satisfy Rule 702, depending solely on whether exclusion had resulted in summary judgment. Neither Rule 104 nor Rule 702, nor Rule 56, Fed. R. Civ. P., authorizes such procedural manipulation. As Chief Justice Marshall wrote for this Court long ago, "It is undoubtedly true, that questions respecting the admissibility of evidence, are entirely distinct from those which respect its sufficiency or effect." *Columbian Ins. Co.* v. *Lawrence*, 2 Pet. 25, 44 (1829).

B. A Standard Disfavoring Summary Judgment Would Undermine Fed. R. Civ. P. 56.

The stringent *Paoli* standard adopted by the Eleventh Circuit here was judicially created to apply only "when the district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment." *Paoli*, 35 F.3d at 750. In other words, the standard is intended to disfavor and discourage rulings that would lead to summary judgment.

Yet there is no policy in the Federal Rules disfavoring summary judgment. Quite the contrary. In *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 322 (1986), this Court explained that "the plain language of Rule 56(c) mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."

> "Summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy and inexpensive determination of every action.'"

Id. at 327, quoting Fed. R. Civ. P. 1; see also *Matsushita Elec. Indus. Co.* v. *Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). "If the evidence is merely colorable . . . or is not significantly probative . . . summary judgment may be granted." *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986); see also *First Nat'l Bank* v. *Cities Service Co.*, 391 U.S. 253, 290 (1968) ("absence of any significant probative evidence").

The Federal Rules expect district judges to "exercise sound discretion and use the tools available" and "be especially alert to identify frivolous claims brought to extort nuisance settlements." *Reiter* v. *Sonotone Corp.*, 442 U.S. 330, 345 (1979). "[E]ven a complaint which by objective standards may have very little chance of success at trial has a settlement value to the plaintiff out of any proportion to its prospect of success at trial so long as he may prevent the suit from being resolved against him by dismissal or summary judgment." *Blue Chip Stamps* v. *Manor Drug Stores*, 421 U.S. 723, 740 (1975); see also Schwarzer, *Summary Judgment Under the Federal Rules*, 99 F.R.D. 465 (1980). The principal drafter of Rule 56 wrote that "a court has failed in granting justice when it forces a party to an expensive trial of several weeks' duration to meet purely formal allegations without substance fully as much as when it improperly refuses to hear a case at all." Clark, *The Summary Judgment*, 36 MINN. L. REV. 567, 578 (1952). Therefore "in Rule 56 proceedings we still apply the manifest-error standard of review to the trial court's evidentiary rulings." *Christophersen* v. *Allied-Signal Corp., supra*, 939 F.2d at 1109. "The abuse of discretion standard applies to an F.R.E. 702 ruling even though the ruling was dispositive of a motion for summary judgment." *Lust* v. *Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 597 (9th Cir. 1996). See also, *e.g.*, *Dyer* v. *MacDougall*, 201 F.2d 265, 268 (2d

Cir. 1952) (L. Hand, J.) (affirming summary judgment where the only evidence identified by plaintiff was inadmissible).

C. "Particularly Stringent" Review Would Discourage District Courts From Performing Their "Gatekeeping" Duty.

A one-way "particularly stringent" review standard would create an incentive structure for district judges that inevitably would discourage the exclusion of opinions lacking scientific support. Under the standard of the Court of Appeals here, if district courts hold opinions admissible, those rulings will receive ordinary abuse-of-discretion deference on appeal. But if district judges perform their "gatekeeping" duty and exclude, then they will be held to a more demanding standard, and are more likely to get reversed. It has been observed that some district judges already are reluctant to grant summary judgment because of the likelihood of reversal if they do so, but not if they deny it.[31] There is no sound basis, particularly in the absence of textual, historical, or functional support, judicially to create further disincentives.

To recognize discretion for district-court admissibility rulings of course does not confer *carte blanche*, or insulate them from meaningful appellate review. This Court in *Wilton* v. *Seven Falls Co.*, *supra*, 115 S. Ct. at 2144, "reject[ed] . . . [the] suggestion . . . that review for abuse of discretion 'is tantamount to no review' at all." See also *Koon* v. *United States*, *supra*, 116 S. Ct. at 2046 ("That the district court retains much of its traditional discretion does not mean appellate review is an empty

[31] See, *e.g.*, Schwarzer, *supra*, at 466-67 ("Trial judges are . . . uncertain about how a summary judgment will fare on appeal . . . . The chilling effect . . . is reinforced by a perception that summary judgments suffer a disproportionately high rate of reversal"). By contrast, a district court's denial of summary judgment normally is unappealable and effectively insulated from reversal. *Cf. Locricchio* v. *Legal Services Corp.*, 833 F.2d 1352, 1359 (9th Cir. 1987) ("After considerable research, we have found no case in which a jury verdict was overturned because summary judgment had been improperly denied").

exercise"); *cf. Beech Aircraft Corp.* v. *Rainey*, 488 U.S. 153, 172 (1988) ("[t]he District Court's refusal to admit the proffered completion evidence was a clear abuse of discretion"); *Old Chief* v. *United States*, 117 S. Ct. 644, 647 (1997) (abuse of discretion under Rule 403); *Clinton* v. *Jones*, 65 U.S.L.W. 4372, 4380 (U.S. 1997) (abuse of discretion to defer trial). And courts of appeals applying an abuse-of-discretion or manifest-error standard have when appropriate reversed district court exclusions under *Daubert*. See, *e.g.*, *United States* v. *14.38 Acres*, 80 F.3d 1074, 1077 (5th Cir. 1996) (reversing exclusion under *Daubert* because "[a]lthough a trial court is accorded a wide berth to determine the admissibility of expert testimony, . . . we conclude that in this case the district court abused its discretion in excluding the testimony"); *Williams* v. *Hedican*, 561 N.W.2d 817, 822 (Iowa 1997); *Tidwell* v. *Upjohn Co.*, 626 So. 2d 1297, 1300 (Ala. 1993); *cf. Buscaglia* v. *United States*, 25 F.3d 530, 534 (7th Cir. 1994) (district court abused its discretion in excluding expert testimony under Rules 702 and 403).

III. THE COURT OF APPEALS MISAPPLIED *DAUBERT*.

The Court of Appeals in second-guessing the District Court's well-supported admissibility ruling not only overstepped its role under Rules 104 and 702, but also misunderstood the requirements of Rule 702 and misapplied *Daubert*.

A. Misplaced Burden of Establishing Admissibility.

For example, the Court of Appeals, whenever it believed information relevant to admissibility was lacking, put the burden of producing it on petitioners. *E.g.*, P.C.A. 13a n.9, 15a; see pp. 36-37, *supra*. But as the dissent recognized, P.C.A. 23a, the law is exactly the opposite. *Daubert* makes clear that for scientific opinions, as for proffers of evidence generally, the burden of establishing admissibility rests on the party seeking to have evidence admitted. "[W]hen the preliminary facts . . . are disputed, the offering party must prove them by a preponderance of the evidence." *Bourjaily* v. *United States*, 483 U.S. 171, 176 (1987), cited in *Daubert*, 509 U.S. at 592 n.10.

B. Self-Validating Experts.

The Court of Appeals observed of Drs. Schecter and Teitelbaum that "each appears to have a national reputation, and the district court qualified them as experts." P.C.A. 8a. It stressed that "the extensive experience and specialized expertise of each of these experts augment the reliability of their reasoning and methodology." P.C.A. 11a. Thus in its "particularly stringent" review of the District Court, the Court of Appeals emphasized a factor not even listed by this Court in *Daubert*. See 509 U.S. at 593-94. In *Daubert* itself, for example, the experts—eight of them—also "possessed impressive credentials," 509 U.S. at 583; nevertheless, on remand their opinions were held not to satisfy Rule 702 because "we've been presented with only the experts' qualifications, their conclusions, and their assurances of reliability. Under *Daubert*, that's not enough." *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1994), *cert. denied*, 116 S. Ct. 189 (1995). "[T]he abuse, or one of the abuses, at which *Daubert* and its sequelae are aimed" is "the hiring of reputable scientists, impressively credentialed, to testify for a fee to propositions that they have not arrived at through the methods that they use when they are doing their regular professional work." *Braun* v. *Lorillard Inc.*, 84 F.3d 230, 234 (7th Cir. 1996).

The Court of Appeals here treated these two experts' opinions as essentially self-validating. The witnesses asserted they had followed scientific methodology, and for the Court of Appeals that was enough, P.C.A. 10a-11a—even though they offered no scientific authority reaching their conclusions, and no response to the scientists who pointed out the omission. See pp. 10-11, *supra*. The Court of Appeals accepted at face value, for instance, Dr. Schecter's unexplained post-deposition assertion that he had "eliminated other potential causes of Joiner's lung cancer to a reasonable degree of medical certainty," P.C.A. 10a, J.A. 404, even though Dr. Schecter gave no hint of how he claimed to have done so, in light of his acknowledgment that "[m]ost lung cancer in the United States is caused by cigarette smoking." J.A. 109.

Even before *Daubert* it was not enough that "the plaintiff's expert brought to court little more than his credentials and a subjective opinion." *Viterbo* v. *Dow Chem. Co.*, 826 F.2d 420, 421 (5th Cir. 1987). Thus in *Daubert* on remand the court of appeals in affirming the district court pointed out, 43 F.3d at 1315-16, that

> "something doesn't become 'scientific knowledge' just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were 'derived by the scientific method' be deemed conclusive, else the Supreme Court's opinion could have ended with footnote two [which summarized the experts' credentials]."

C. Absence of Scientific Methodology.

"In a case involving scientific evidence, *evidentiary reliability* will be based upon *scientific validity*." *Daubert*, 509 U.S. at 591 n.9 (emphasis in original). As this Court explained,

> "The adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation."

509 U.S. at 590. "[T]he Supreme Court in *Daubert* told judges to distinguish between real and courtroom science." *Rosen* v. *Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir.), *cert. denied*, 117 S. Ct. 73 (1996).

The District Court here examined the opinions and pointed out "the analytical gap between the evidence presented and the inferences to be drawn." P.C.A. 61a, quoting *Turpin* v. *Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir.), *cert. denied*, 506 U.S. 826 (1992). The Court of Appeals, however, treated *Daubert's* requirement of scientific methodology at such a superficial level as to leave it meaningless—calling for no more than the invocation of scientific materials. Thus the Court of Appeals simply referred without elaboration to "the studies of at least thirteen different researchers . . . that *address* the question of whether PCBs cause cancer,"

as if this somehow turned the experts' conjectures into "scientific . . . knowledge." P.C.A. 12a (emphasis supplied). The Court of Appeals essentially held that if an expert cites conventional scientific authorities, the expert has satisfied the requirement of scientific methodology, no matter what the authorities actually say, and what steps are missing between the citations and the conclusion.

If this Court's *Daubert* opinion made anything clear, it was that Rule 702 does not permit experts' opinions to escape methodological scrutiny simply by invoking a black box called science. "To the contrary, under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." 509 U.S. at 589. Under *Daubert*, scientific *methodology* requires scientific *reasoning*, which includes as a minimum that conclusions be logically supported by premises. In addition, "the scientific method" consists of "subjecting testable hypotheses to the crucible of experiment in an effort to disprove them." *United States* v. *Bynum*, 3 F.3d 769, 773 (4th Cir. 1993), *cert. denied*, 510 U.S. 1132 (1994). "Ordinarily, a key question . . . in determining whether a theory or technique is scientific knowledge . . . will be whether it can be (and has been) tested." *Daubert*, 509 U.S. at 593.

No empirical tests had reached the conclusions offered by these witnesses. That was not from absence of trying. PCBs have been widely and repeatedly tested for many years now—with no study concluding that they caused human cancer, much less small-cell lung cancer. *E.g.* J.A. 169-70, 234-35, 238, 271, 279, 307, 371, 375-76, 378, 381-82; see generally Kimbrough, *The Human Health Effects of Polychlorinated Biphenyls*, in K. FOSTER *et al.*, PHANTOM RISK 221, 221-25 (1993). " '[G]eneral acceptance' can yet have a bearing," and a tested hypothesis lacking it "may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594.

The Court of Appeals, referring to animal studies and surmises, reversed the District Court on the ground that

> "[o]pinions of any kind are derived from individual pieces of evidence, each of which by itself might not be conclusive, but when viewed in their entirety are the building blocks of a perfectly reasonable conclusion . . . ."

P.C.A. 12a. Almost those very words have been cited by scientists and scholars as violating the methodology of science: "The faggot fallacy is a belief that multiple pieces of evidence, each independently being suspect or weak, provide strong evidence when bundled together." P. SKRABANEK & J. MCCORMICK, FOLLIES & FALLACIES IN MEDICINE 35 (1990), quoted in K. FOSTER & P. HUBER, *supra*, at 142.

In other circuits district-court exclusions of unsupported opinions have repeatedly been affirmed. *E.g.*, *Sorensen* v. *Shakelee Corp.*, 31 F.3d 638, 649 (8th Cir. 1994):

> "Here, the hypotheses presented by plaintiffs' experts follow no scientific principles. . . . Instead of reasoning from known facts to reach a conclusion, the experts here reasoned from an end result in order to hypothesize what needed to be known but what was not."

See also, *e.g.*, *Deimer* v. *Cincinnati Sub-Zero Prods. Inc.*, 58 F.3d 341, 344-45 (7th Cir. 1995) ("the witness did not conduct any studies or analysis to substantiate his opinion. . . . The witness proffered unverified statements that were unsupported by any scientific method"); *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d at 1319 ("Dr. Palmer offers no tested or testable theory to explain how, from this limited information, he was able to eliminate all other potential causes of birth defects, nor does he explain how he alone can state as a fact that Bendectin caused plaintiffs' injuries"), *cert. denied*, 116 S. Ct. 189 (1995); *O'Conner* v. *Commonwealth Edison Co.*, 13 F.3d 1090, 1106 (7th Cir.) ("In order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method"), *cert. denied*, 512 U.S. 1222 (1994); *Viterbo* v. *Dow Chem. Co.*, 826 F.2d 420, 424 (5th Cir. 1987) ("Dr. Johnson's testimony is no more

than Viterbo's testimony dressed up and sanctified as the opinion of an expert").

"[A] scientist, however reputable, is not permitted to offer evidence that he has not generated by the methods he would use in his normal academic or professional work . . . ." *Khan* v. *State Oil Co.*, 93 F.3d 1358, 1365 (7th Cir. 1996), *cert. granted*, 117 S. Ct. 941 (1997). Opinions to be admissible under Rule 702 must be "genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist." *Rosen* v. *Ciba-Geigy Corp.*, *supra*, 78 F.3d at 318.[82]

CONCLUSION

For the reasons stated, the judgment of the Court of Appeals should be reversed.

Respectfully submitted,

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[82] "[C]ourts must be particularly wary of unfounded expert opinion testimony when medical causation is the issue. As we have previously noted, 'there is not much difficulty in finding a medical expert witness to testify to virtually any theory of medical causation short of the fantastic.'"

Cella v. *United States*, 998 F.2d 418, 423 (7th Cir. 1993), quoting *Stoleson* v. *United States*, 708 F.2d 1217, 1222 (7th Cir. 1983). See also *In re Air Crash Disaster*, 795 F.2d 1230, 1234 (5th Cir. 1986) ("opinions that they might not be willing to express in an article submitted to a refereed journal"); *Mid-State Fertilizer Co.* v. *Exchange Nat'l Bank*, 877 F.2d 1333, 1340 (7th Cir. 1989) ("ukase in the guise of expertise is a plague in contemporary litigation"); Berger, *A Relevancy Approach to Novel Scientific Evidence*, 115 F.R.D. 89, 91 (1987) ("It is quite apparent that experts are readily available to present essentially frivolous theories . . . ."); Weinstein, *Improving Expert Testimony*, 20 U. RICH. L. REV. 473, 482 (1986) ("[a]n expert can be found to testify to the truth of almost any factual theory, no matter how frivolous . . . ."). *Cf. Winans* v. *New York & E.R.R.*, 21 How. 88, 101 (1859) ("opposite opinions of persons professing to be experts may be obtained to any amount").

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APPENDIX

APPENDIX

A. FEDERAL RULES OF EVIDENCE

Rule 104

Preliminary Questions

(a) Questions of Admissibility Generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

(b) Relevancy conditioned on fact. When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

(c) Hearing of jury. Hearings on the admissibility of confessions shall in all cases be conducted out of the hearing of the jury. Hearings on other preliminary matters shall be so conducted when the interests of justice require, or when an accused is a witness and so requests.

(d) Testimony by accused. The accused does not, by testifying upon a preliminary matter, becomes subject to cross-examination as to other issues in the case.

(e) Weight and credibility. This rule does not limit the right of a party to introduce before the jury evidence relevant to weight or credibility.

* * * *

Rule 401

Definition of "Relevant Evidence"

"Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

Rule 402

Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 403

Exclusion of Relevant Evidence on Grounds of Prejudice, Confusion, or Waste of Time

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

* * * *

Rule 701

Opinion Testimony by Lay Witnesses

If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness and (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue.

Rule 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Rule 703

Bases of Opinion Testimony by Experts

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Rule 704

Opinion on Ultimate Issue

(a) Except as provided in subdivision (b), testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.

(b) No expert witness testifying with respect to the mental state or condiiton of a defendant in a criminal case may state an opinion or inference as to whether the defendant did or did not have the mental state or condition constituting an element of the crime charged or of a defense thereto. Such ultimate issues are matters for the trier of fact alone.

Rule 705

Disclosure of Facts or Data Underlying Expert Opinion

The expert may testify in terms of opinion or inference and give reasons therefor without first testifying to the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination.

Rule 706

Court Appointed Experts

(a) Appointment. The court may on its own motion or on the motion of any party enter an order to show cause why expert witnesses should not be appointed, and may request the parties to submit nominations. The court may appoint any expert witnesses agreed upon by the parties, and may appoint expert witnesses of its own selection. An expert witness shall not be appointed by the court unless the witness consents to act. A witness so appointed shall be informed of the witness' duties by the court in writing, a copy of which shall be filed with the clerk, or at a conference in which the parties shall have opportunity to participate. A witness so appointed shall advise the parties of the witness' findings, if any; the witness' deposition may be taken by any party; and the witness may be called to testify by the court or any party. The witness shall be subject to cross-examination by each party, including a party calling the witness.

(b) Compensation. Expert witnesses so appointed are entitled to reasonable compensation in whatever sum the court may allow. The compensation thus fixed is payable from funds which may be provided by law in criminal cases and civil actions and proceedings involving just compensation under the fifth amendment. In other civil actions and proceedings the compensation shall be paid by the parties in such proportion and at such time as the court directs, and thereafter charged in like manner as other costs.

(c) Disclosure of appointment. In the exercise of its discretion, the court may authorize disclosure to the jury of the fact that the court appointed the expert witness.

(d) Parties' experts of own selection. Nothing in this rule limits the parties in calling expert witnesses of their own selection.

* * * *

Rule 1101

Applicability of Rules

(a) Courts and judges. These rules apply to the United States district courts, the District Court of Guam, the District Court of the Virgin Islands, the District Court for the Northern Mariana Islands, the United States courts of appeals, the United States Claims Court, and to United States bankruptcy judges and United States magistrate judges, in the actions, cases, and proceedings and to the extent hereinafter set forth. The terms "judge" and "court" in these rules include United States bankruptcy judges and United States magistrate judges.

(b) Proceedings generally. These rules apply generally to civil actions and proceedings, including admiralty and maritime cases, to criminal cases and proceedings, to contempt proceedings except those in which the court may act summarily, and to proceedings and cases under title 11, United States Code.

(c) Rule of privilege. The rule with respect to privileges applies at all stages of all actions, cases, and proceedings.

(d) Rules inapplicable. The rules (other than with respect to privileges) do not apply in the following situations.

(1) Preliminary questions of fact. The determination of questions of fact preliminary to admissibility of evidence when the issue is to be determined by the court under rule 104.

(2) Grand jury. Proceedings before grand juries.

(3) Miscellaneous proceedings. Proceedings for extradition or rendition; preliminary examinations in criminal cases; sentencing, or granting or revoking probation; issuance of warrants for arrest, criminal summonses, and search warrants; and proceedings with respect to release on bail or otherwise.

* * * *

B. FEDERAL RULES OF CIVIL PROCEDURE

Rule 1

Scope and Purpose of Rules

These rules govern the procedure in the United States district courts in all suits of a civil nature whether cognizable as cases at law or in equity or in admiralty, with the exceptions stated in Rule 81. They shall be construed and administered to secure the just, speedy, and inexpensive determination of every action.

* * * *

Rule 56

Summary Judgment

(a) For Claimant. A party seeking to recover upon a claim, counterclaim, or cross-claim or to obtain a declaratory judgment may, at any time after the expiration of 20 days from the commencement of the action or after service of a motion for summary judgment by the adverse party, move with or without supporting affidavits for a summary judgment in the party's favor upon all or any part thereof.

(b) For Defending Party. A party against whom a claim, counterclaim, or cross-claim is asserted or a declaratory judgment is sought may, at any time, move with or without supporting affidavits for a summary judgment in the party's favor as to all or any part thereof.

(c) Motion and Proceedings Thereon. The motion shall be served at least 10 days before the time fixed for the hearing. The adverse party prior to the day of hearing may serve opposing affidavits. The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. A summary

judgment, interlocutory in character, may be rendered on the issue of liability alone although there is a genuine issue as to the amount of damages.

(d) Case Not Fully Adjudicated on Motion. If on motion under this rule judgment is not rendered upon the whole case or for all the relief asked and a trial is necessary, the court at the hearing of the motion, by examining the pleadings and the evidence before it and by interrogating counsel, shall if practicable ascertain what material facts exist without substantial controversy and what material facts are actually and in good faith controverted. It shall thereupon make an order specifying the facts that appear without substantial controversy, including the extent to which the amount of damages or other relief is not in controversy, and directing such further proceedings in the action as are just. Upon the trial of the action the facts so specified shall be deemed established, and the trial shall be conducted accordingly.

(e) Form of Affidavits; Further Testimony; Defense Required. Supporting and opposing affidavits shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein. Sworn or certified copies of all papers or parts thereof referred to in an affidavit shall be attached thereto or served therewith. The court may permit affidavits to be supplemented or opposed by depositions, answers to interrogatories, or further affidavits. When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party.

(f) When Affidavits are Unavailable. Should it appear from the affidavits of a party opposing the motion that the party cannot for reasons stated present by affidavit facts essential to justify the party's opposition, the court may refuse the application for judgment or may order a continuance to permit affidavits to be obtained or depositions to be taken or discovery to be had or may make such other order as is just.

(g) Affidavits Made in Bad Faith. Should it appear to the satisfaction of the court at any time that any of the affidavits presented pursuant to this rule are presented in bad faith or solely for the purpose of delay, the court shall forthwith order the party employing them to pay to the other party the amount of the reasonable expenses which the filing of the affidavits caused the other party to incur, including reasonable attorney's fees, and any offending party or attorney may be adjudged guilty of contempt.

C. STATE RULES OF EVIDENCE

Alaska Rule of Evidence 702

TESTIMONY BY EXPERTS

(a) If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

* * * *

Arizona Rule of Evidence 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Arkansas Rule of Evidence 702

TESTIMONY BY EXPERTS

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Colorado Rule of Evidence 702

TESTIMONY BY EXPERTS

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Delaware Rule of Evidence 702

TESTIMONY BY EXPERTS.

If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise.

Florida Statutes § 90.702

Testimony by experts.

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion; however, the opinion is admissible only if it can be applied to evidence at trial.

Hawaii Rule of Evidence 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise. In determining the issue of assistance to the trier of fact, the court may consider the trustworthiness and validity of the scientific technique or mode of analysis employed by the proffered expert.

Idaho Rule of Evidence 702

Testimony by experts.

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an

expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Indiana Rule of Evidence 702

TESTIMONY BY EXPERTS

(a) If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

(b) Expert scientific testimony is admissible only if the court is satisfied that the scientific principles upon which the expert testimony rests are reliable.

Kentucky Rule of Evidence 702

Testimony by experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Louisiana Code of Evidence, Article 702

Testimony by experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Maine Rule of Evidence 702

TESTIMONY BY EXPERTS

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise.

Michigan Rule of Evidence 702

TESTIMONY BY EXPERTS

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. The court may require that underlying facts or data essential to an opinion or inference be in evidence.

Minnesota Rule of Evidence 702

TESTIMONY BY EXPERTS

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise.

Missouri Revised Statutes § 490.065

Expert witness, opinion testimony admissible —hypothetical question not required, when

1. In any civil action, if scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise.

* * * *

Montana Rule of Evidence 702

TESTIMONY BY EXPERTS

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Nebraska Rule of Evidence 702

TESTIMONY BY EXPERTS; WHEN

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Nevada Revised Statutes Annotated § 50.275

Testimony by experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by special knowledge, skill, experience, training, or education, may testify to matters within the scope of such knowledge.

New Hampshire Rule of Evidence 702

TESTIMONY BY EXPERTS

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

New Jersey Rule of Evidence 702

Testimony by Experts.

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

New Mexico Rule of Evidence 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

North Carolina Rule of Evidence 702

Testimony by Experts

(a) If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion.

* * * *

North Dakota Rule of Evidence 702

TESTIMONY BY EXPERTS

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Ohio Rule of Evidence 702

Testimony by Experts

A witness may testify as an expert if all of the following apply:

(A) The witness' testimony either relates to matters beyond the knowledge or experience possessed by lay persons or dispels a misconception common among lay persons;

(B) The witness is qualified as an expert by specialized knowledge, skill, experience, training, or education regarding the subject matter of the testimony;

(C) The witness' testimony is based on reliable scientific, technical, or other specialized information. To the extent that the testimony reports the result of a procedure, test, or experiment, the testimony is reliable only if all of the following apply:

(1) The theory upon which the procedure, test, or experiment is based is objectively verifiable or is validly derived from widely accepted knowledge, facts, or principles;

(2) The design of the procedure, test, or experiment reliably implements the theory;

(3) The particular procedure, test, or experiment was conducted in a way that will yield an accurate result.

12 Oklahoma Statutes § 2702

Testimony by Experts

If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Oregon Evidence Code § 240.410, Rule 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Rhode Island Rule of Evidence 702

Testimony by experts.—If scientific, technical, or other specialified knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of fact or opinion.

South Carolina Rule of Evidence 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise.

South Dakota Codified Laws § 219-15-2, Rule 702

Opinions of Experts Admissible

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Tennessee Rule of Evidence 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will substantially assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise.

Texas Rule of Civil Evidence 702

TESTIMONY BY EXPERTS

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise.

Utah Rule of Evidence 702

Testimony by experts.

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Vermont Rule of Evidence 702

TESTIMONY BY EXPERTS

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Washington Rule of Evidence 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

West Virginia Rule of Evidence 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Wisconsin Statutes § 907.02

Testimony by experts.

If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Wyoming Rule of Evidence 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill experience, training, or education, may testify thereto in the form of an opinion or otherwise.

(20)

No. 96-188

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

October Term, 1996

GENERAL ELECTRIC COMPANY, WESTINGHOUSE ELECTRIC CORPORATION, AND MONSANTO COMPANY,
Petitioners,

v.

ROBERT K. JOINER AND KAREN P. JOINER,
Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR RESPONDENTS

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QUESTION PRESENTED

What is the standard of appellate review for trial court decisions excluding expert testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)?

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BRIEF FOR RESPONDENTS

STATEMENT

Respondent Robert K. Joiner was diagnosed with lung cancer in 1991 at age 37. He and his wife (respondent Karen P. Joiner) filed suit, alleging that products manufactured and sold by petitioners, to which Joiner had been exposed occupationally, had contributed to his unusually early onset of lung cancer.[1]

A. Factual Background

Petitioner Monsanto Company was the sole manufacturer of polychlorinated biphenyls ("PCBs") in the United States from 1935 until 1977, when PCBs were banned by federal law. App. 36a. PCBs are man-made chemicals that were purchased during this period by petitioners General Electric Company ("GE") and Westinghouse Electric Corporation for use as a component of fire-resistant dielectric fluid in electrical transformers that they marketed to utilities. PCBs have long been regarded as extremely hazardous to humans and, in particular, as being "highly toxic carcinogen[s]." *Midlantic Nat'l Bank v. New Jersey Dep't of Envtl. Protection*, 474 U.S. 494, 497 (1986).[2] They are classified as

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[1] References to the appendix attached to the petition for certiorari are styled "App. __a," and to the Joint Appendix, "J.A. __." References to the supplemental appendix that appears at the end of this brief, containing record excerpts pertinent to arguments advanced by petitioners in their merits brief that were not raised in the petition, see note 52, *infra*, are styled "S.A. __." References to "Joiner" denote respondent Robert K. Joiner, not respondent Karen P. Joiner, unless otherwise indicated.

[2] *See* Toxic Substances Control Act, 15 U.S.C. § 2605(a) & (e) (1976) (banning the production and sale of PCBs, with narrow exceptions, effective January 1, 1978, based on congressional finding that "there is a reasonable basis to conclude that [PCBs] present[] or will present an unreasonable risk of injury to health or the environment"); *Yaffe Iron & Metal Co., Inc. v. EPA*, 774 F.2d 1008, 1010 n.1 (10th Cir. 1985) ("PCBs are extremely toxic to humans and wildlife, and pose carcinogenic and other risks to humans"); *Environmental Defense Fund, Inc. v. EPA*, 636 F.2d 1267, 1270 (D.C. Cir. 1980) ("Epidemiological data and experiments on laboratory animals indicate that

probable human carcinogens by federal and international health authorities.[3]

Routinely present in transformers containing PCBs were two chemical derivatives of PCBs produced in the process of manufacturing them and through heat and other conditions present during their use: polychlorinated dibenzofurans ("furans") and, to a lesser extent, polychlorinated dibenzodioxins ("dioxins"). The parties' experts agreed on this point, although they disagreed about the amounts of these contaminants typically present in the transformers along with PCBs.[4] Furans and dioxins are even more

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exposure to PCBs pose[s] carcinogenic and other risks to humans."); *Environmental Defense Fund v. EPA*, 598 F.2d 62, 76 & n.54 (D.C. Cir. 1978) (summarizing legislative history of ban on PCBs).

[3] *See, e.g.*, 62 FED. REG. 24887, 24891 (May 7, 1997) ("PCBs are classified as [Class I], group B2, probable human carcinogens by EPA and are listed as substances which may reasonably be anticipated to be human carcinogens in the NIEHS/NTP Annual Report on Carcinogens.") (citations omitted); 54 FED. REG. 22062, 22089 (May 22, 1989) ("There are several animal studies which show PCB mixtures to be carcinogenic. As discussed in the November 1985 proposal, EPA believes these studies are sufficient to classify PCBs in Group B2, probable human carcinogen. . . . Three recently published epidemiologic studies of PCB-exposed populations reported statistically significant excesses of tumors of the lung, liver, gastrointestinal tract and hematopoietic system."). In 1987, the International Agency for Research on Cancer (IARC) of the World Health Organization, after considering "the combined evidence from human and experimental animal studies . . . concluded that PCBs are probably carcinogenic for humans." WORLD HEALTH ORGANIZATION, POLYCHLORINATED BIPHENYLS AND TERPHENYLS 478 (2d ed. 1993) ("hereinafter "WHO"); *see also* S.A. 10, 16, 22 (Teitelbaum); S.A. 62 (Cole). One of petitioners' experts acknowledged, with remarkable understatement, that "there are credible scientists who hold the view that PCBs are an established human carcinogen." J.A. 235 (Cole).

[4] Joiner's experts, in a portion of their testimony that petitioners never sought to exclude as inadmissible, testified to the routine presence of these contaminants in PCB transformer fluids. *See* J.A. 405 (Schecter) (furans "are usually found in PCB transformer fluids, as reported in numerous reports and at many scientific meetings"); S.A. 49 (Schecter) (additional furans, and some dioxin, are created from heating of the PCBs during their use); J.A. 456 (Teitelbaum) (furans "are generally believed to contaminate all transformers at varying concentrations when PCBs, oxygen, and electric current combine," as a result of lightning strikes, overheating, fires and arcing of transformers). GE's

carcinogenic than PCBs.[5]

Joiner's complaint alleged that during the period in which GE and Westinghouse were manufacturing transformers containing PCB dielectric fluid, they and Monsanto were all aware of the dangers.[6] "Health problems associated with the manufacture of PCBs" were reported in the literature as early as 1936, with the first fatalities in workers reported in 1937, in a study warning that typical levels of occupational exposure to PCBs were unsafe.[7]

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top scientist on PCBs agreed that furans and dioxins "were not intentional constituents, but they have always been there" in its PCB-based dielectric fluids, although he opined that the amounts were "toxicologically insignificant." S.A. 73 (Brown). *See also* S.A. 64-65 (Hamilton). One of the leading scientific references on the subject, cited by petitioners, states that furans "are contaminants in commercial PCB mixtures . . . at levels ranging from a few mg/kg up to 40 mg/kg," and that these furans "contribute significantly to" the toxicity of the PCB mixtures. WHO, *supra* note 3, at 21-22 (cited in Pet. Br. 3 n.2).

[5] *See, e.g.*, 62 FED. REG. 24887, 24891 (May 7, 1997) (noting evidence that dioxins are "a potent carcinogen," indeed, based on one EPA analysis, "the most potent chemical carcinogen that EPA has regulated); CHEMICAL WEEK, Apr. 16, 1997, at 8 ("[D]ioxin's toxicological and regulatory profile is growing. . . . Cancer risk remains significant: In February the International Agency for Research on Cancer upgraded the most potent form of dioxin from a 'probable' to a 'known' human carcinogen."); Dieter Flesch-Janys, et al., *Exposure to Polychlorinated Dioxins and Furans (PCDD/F) and Mortality in a Cohort of Workers from a Herbicide-Producing Plan in Hamburg, Federal Republic of Germany*, 142 AM. J. OF EPIDEMIOLOGY 1165, (1995) (epidemiological study further confirming "the strong existing evidence of a carcinogenic effect of [furans and dioxins] in humans."). Petitioners' experts agreed on this point. *See, e.g.*, S.A. 65 (Hamilton) ("I believe that [furans] pose potential health risks to humans"); S.A. 73 (Brown) (dioxins are "a very potent agent" in promoting cancer).

[6] J.A. 68 (First Amended Complaint ¶ 6). Petitioners did not controvert these allegations in their motion for summary judgment.

[7] U.S. DEP'T OF HEALTH, EDUCATION & WELFARE, OCCUPATIONAL EXPOSURE TO POLYCHLORINATED BIPHENYLS (PCBS) 31-32 & nn. 120, 125 (1977) (hereinafter "HEW") (cited in Pet. Br. 3 n.2). *See also* WHO, *supra* note 3, at 19 (noting that commercial production of PCBs "began in 1930, and, during the 1930s, cases of poisoning were reported among men engaged in their manufacture . . . in some cases with fatal consequences.").

In 1975 Monsanto learned from a study of its workers involved in the manufacture of PCBs that "[t]he mortality due to lung cancer" ranged "from between three- and ten-fold, when compared to the figure expected, and the increased rate is significant." S.A. 80. *See also* S.A. 82 (followup analysis describing "highly significant" epidemiological evidence of a tripling of lung cancer risk). A separate 1976 Monsanto study provided further indications of a tripling of lung cancer risk associated with PCB exposure. S.A. 84. Monsanto continued producing PCBs for use in dielectric fluid until 1977, when it was forced to stop by federal law.

As for Westinghouse, as early as 1945 it warned its workers not to breathe vapors from its PCB fluids and to "avoid contact of it with the skin." S.A. 75. In 1947 it warned plant managers that the fluids were "highly toxic," posing a danger of "[c]hronic poisoning" that "could be fatal," and that "[c]are must be taken to prevent any appreciable contact of this material with the skin," and to use a combination of ventilation and/or respirators given the dangers posed by breathing in the vapors. S.A. 77-78. Although the current record on GE's knowledge of the hazards of PCBs, and the need for careful efforts to protect workers, is not nearly as extensive as on Westinghouse's knowledge, it does reflect that, by 1975, GE had at least one scientist in charge of studying safety concerns over PCBs, S.A. 73 (Brown), and that during this period GE had discussions with Westinghouse concerning the issue.[8]

PCB-based dielectric fluids were only used intentionally to build transformers that would operate in areas unusually subject to fire dangers, so that less than 0.2% of transformers in use by utilities nationwide were manufactured with the intent that they

[8] Deposition of Thomas O. Rouse at 73, 89. Early in the litigation the district court, with the parties' consent, stayed all discovery except with respect to the issue of causation. J.A. 59-66. It is clear, however, that by 1977 the need for careful precautions against occupational exposure to PCBs had become well established in the field. *See, e.g.*, HEW, *supra* note 7, at 145-46 (noting that "[t]he carcinogenic, teratogenic, dermatologic, and fetotoxic effects of PCBs" require the posting of warning signs, "[a]dequate ventilation," and the use of "PCB-resistant protective clothing and equipment, including respirators," among other precautions).

contain any PCBs or their typical furan and dioxin derivatives. App. 35a. Nearly all transformers manufactured by GE and Westinghouse were filled with dielectric fluid using mineral oil that should have been entirely free of such hazards. By the mid 1970s, however, both GE and Westinghouse had discovered that many millions of the mineral oil transformers that they had sold to utilities over the decades and that were still in service were contaminated with PCBs, as the result of negligent manufacturing techniques that had allowed improper mixing of the two types of dielectric fluids.[9]

Despite their knowledge that millions of their supposedly PCB-free mineral oil transformers were contaminated with PCBs, furans and dioxins, both GE and Westinghouse continued for years to provide warning labels and safety guidelines *only* with respect to the 0.2% of transformers that they specifically manufactured to contain PCBs.[10]

B. The Present Action

In 1973, when GE and Westinghouse were learning that many of the mineral oil transformers they had placed in service were contaminated with PCBs, furans and dioxins, respondent Robert K. Joiner began working as an electrician for the City of Thomasville, Georgia. Joiner's duties included working with and around electrical transformers manufactured by GE and Westinghouse, all

[9] J.A. 70-71 (First Amended Complaint ¶¶ 14, 18). *See also* 52 FED. REG. 10688, 10695 (Apr. 2, 1987) ("EPA estimates that there are . . . over 20 million mineral oil transformers contaminated with PCBs currently in use"); S.A. 6 (Teitelbaum). *See, e.g.*, Exhibit 12 to Opposition to Summary Judgment (letter to industry purchasing executives from Westinghouse marketing manager D.P. Keiser, dated Nov. 22, 1976); S.A. 69-70 (Rouse); S.A. 71 (Rouse) (stating that at GE plant, "[a] transformer could be inadvertently filled with [PCBs] and drained into a [mineral] oil line; equally so, a transformer could be inadvertently drained with [mineral] oil and drained into the [PCB] line. . . . [I]n all cases, these kinds of actions of mixing were unintentional. . . . I think you could characterize them as mistakes.").

[10] J.A. 71 (First Amended Complaint ¶¶ 17-19). *See, e.g.*, S.A. 53 (Joiner); Deposition of Thomas O. Rouse at 55-56.

of which used mineral oil dielectric fluid. App. 2a. Because Joiner's employer had received no indication that the supposedly PCB-free transformers contained any PCBs, furans or dioxins, Joiner took none of the precautions that had by then become well established as necessary for those working with these hazardous substances.[11] In repairing the transformers, Joiner routinely stuck his bare hands and arms into the toxic fluids and breathed in their heated fumes, and they often splashed over his body and sometimes into his eyes and mouth.[12]

By the late 1980s, as a result of testing done by Joiner's employer, it was discovered that approximately half of the supposedly PCB-free transformers were contaminated with PCBs, with approximately 20 percent of all transformers contaminated at levels considered extremely hazardous by the EPA. App. 2a, 36a.[13] Only then, after Joiner had been handling contaminated transformers for about fourteen years, did he finally receive the safety equipment and training necessary to handle them safely. J.A. 208-09 (Joiner); S.A. 51 (Joiner).

In 1991, Joiner was diagnosed with lung cancer, a remarkable occurrence given that he was only age 37, had a relatively brief smoking history, and had quit smoking a decade earlier. App. 3a & n.3. Expert testimony that petitioners never sought to exclude as inadmissible established that "lung cancer is extremely rare for a thirty seven year old white male in the United States" and in this case is the probable "result of exposure to other exogenous factors which lead to the rapid development of the malignancy," which are "often referred to as promoters and are what make, or promote, an essentially harmless initiated cell into a harmful malignant cancer." J.A. 444-45 (Frank). *See also* J.A. 453 (Teitelbaum) ("it is clearly

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[11] J.A. 71 (First Amended Complaint ¶ 19). *See, e.g.* J.A. 208, 211, 217-18 (Joiner); S.A. 51-53 (Joiner).

[12] App. 2a-3a & n.2, 37a. *See also* J.A. 207-08, 211-15, 218-19 (Joiner); S.A. 50-52 (Joiner); S.A. 8, 12 (Teitelbaum); S.A. 40, 48 (Schecter).

[13] According to one of petitioners' experts, the percentage of contaminated transformers was even higher earlier during Joiner's employment. S.A. 70 (Rouse).

extraordinary for lung cancer to develop in a 37 year old male with a brief smoking history which terminated eleven years prior to the onset of his cancer," strongly pointing "to the operation of other carcinogens and cocarcinogens in Mr. Joiner's cancer, since cigarette smoking is so unlikely to be a sufficient cause of lung cancer at his age"); J.A. 445 (Frank) ("It is more likely than not . . . that tobacco smoke served only as the initator of [Joiner's] cancer and that some other agent served as the promoter of the initated cells").[14]

Joiner and his wife filed suit against petitioners seeking damages on the basis that Joiner's exposure to PCBs and their derivatives, to which he had been exposed as a result of the contaminated transformers that he had worked with, had been a probable contributing factor to his early development of lung cancer.[15] The parties are in agreement that under Georgia law, Joiner may prevail even if his lung cancer would not have occurred but for his cigarette smoking, and even if he eventually would have contracted lung cancer, if he can prove that petitioners' products in some way aggravated his existing susceptibility to cancer, e.g., by accelerating its onset.[16]

C. Joiner's Expert Testimony on Causation

During discovery, Joiner produced two expert witnesses in support of his claim that transformers manufactured by GE and Westinghouse, containing PCBs, furans and dioxins manufactured by Monsanto, had contributed to his development of lung cancer.

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[14] One of petitioners' experts recently observed that even "a man who quits [cigarette smoking] at age 40" (more than a decade after Joiner quit) "will live on average 99% as long as a man who never smoked." Brad Rodu and Philip Cole, *The Rewards of Smoking Cessation*, 7 EPIDEMIOLOGY 111 (1996) (letter).

[15] J.A. 69-75 (First Amended Complaint ¶¶ 10-36).

[16] *See* Brief of Appellants, No. 94-9131, 11th Cir., at 7-10 (summarizing relevant law); Brief of Appellees at 34 (stating that "defendants [have never] contended that the plaintiffs must prove that PCBs were the 'sole' cause of Mr. Joiner's illness," and conceding that Joiner need only show that his cancer "was promoted by his exposure to PCBs"). *See, e.g., Holley v. Smallwood*, 330 S.E.2d 136, 136-37 (Ga. App. 1985).

Dr. Teitelbaum. Daniel T. Teitelbaum, M.D., a co-founder of both the American Academy of Clinical Toxicology and the American Board of Medical Toxicology, is a toxicology expert who teaches a variety of graduate-level courses in occupational and environmental toxicology and the epidemiology of toxic diseases. J.A. 447-48, 473. He has published more than forty articles on these subjects in peer-reviewed journals and has served as an editorial board member or reviewer for several peer-reviewed journals. J.A. 448, 477-83. Teitelbaum devotes 40 percent of his time to teaching and patient care and 60 percent of his time to consulting for the federal government, major corporations, and private individuals.[17] Teitelbaum frequently treats patients from the electrical trades and, as a result of this work, has "extensive knowledge of the handling of toxic substances, hazardous materials, electrical power, and other risks of a physical and chemical nature." J.A. 449.

Teitelbaum explained in detail the methodology he used to form an opinion on whether petitioners' products had probably contributed to the development of Joiner's lung cancer. He conducted "a comprehensive and traditional occupational medical assessment" of Joiner, utilizing "traditional medical assessment techniques," in which he spent several hours examining Joiner and

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[17] J.A. 169. In his consulting work, Teitelbaum has assisted a number of federal agencies in assessing the toxicity of chemicals and other substances — serving as chairman of an FDA panel, as a member of several EPA committees or panels, as a special consultant to OSHA on many occasions, and as a member of a blue-ribbon presidential panel that was formed to chart strategy for future EPA and NIH research concerning the health risks of emerging technologies. J.A. 447-48, 476-77. He has served as an advisor or panel member of several World Health Organization working groups and has taught federal judges on the subjects of toxicology and epidemiology, under the auspices of the Federal Judicial Center. J.A. 448. He has consulted on occupational and environmental toxicology issues for IBM, W.R. Grace, Amoco, Xerox, Motorola and Intel. J.A. 473. Despite petitioners' efforts to depict Teitelbaum as engaged in the full time delivery of expert testimony for tort plaintiffs, *see* Pet. Br. 7, he testifies, on average, at only three or four trials a year, and in some years he does not appear in court at all. J.A. 168.

taking his medical history;[18] reviewed Joiner's medical records; reviewed data on Joiner's workplace exposure to hazardous chemicals and other risk factors; and relied on his general knowledge of the field and his literature review of the health effects of PCBs and their derivatives, in combination with the above data, to reach a conclusion. J.A. 449-50; S.A. 3-12, 15-19; *see also* App. 9a (quoting summary of methodology).

When asked at his deposition whether his methodology constituted valid toxicology, Teitelbaum testified to the difference between the term "probable" as it is "used by epidemiologists" and "probable" as it is "used by clinicians," which "is what most of the world runs on. That is to say you look at all the information and you come to a conclusion that all the evidence together gives you the reasonable likelihood that your conclusion is clinically correct," producing "a valid conclusion based on the totality of the evidence presented," which "is an appropriate thing for a toxicologist to do." S.A. 18-19.

Based on this methodology, Teitelbaum concluded that it was probable that Joiner's "lung cancer was caused or contributed to in a significant degree by the materials with which he worked," including specifically PCBs and furans, S.A. 6, and that Joiner's "work with PCB contaminated mineral oil, mineral spirits, and mineral oil per se," along with "his family history" and "his smoking history," combined in a "multifactorial fashion . . . to result in lung cancer at a very young age in a minimal smoker." J.A. 455. *See also* J.A. 451, 461; S.A. 8-11; Deposition at 47-65.

None of the three experts designated by petitioners on the causation issue disagreed with any aspect of Teitelbaum's methodology, or with his application of the methodology, or with the types of data that he relied upon.[19] Indeed, these experts used

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[18] Teitelbaum traveled to Atlanta, where he conducted a full-scale examination in a physician's office outside the presence of any lawyers. J.A. 449; S.A. 3-4, 21. *But see* Pet. Br. 36 (asserting without any evidence that Teitelbaum simply met Joiner "at the lawyers' office").

[19] The only expert for petitioners who made even passing reference to Dr. Teitelbaum's testimony stated that he had not reviewed Teitelbaum's deposition

the very same methodology as Teitelbaum — they looked at the same sources of information as Teitelbaum, and engaged in inductive reasoning to assess the likelihood that these substances had promoted Joiner's cancer — and differed with Teitelbaum only as to the conclusion they reached using this methodology.[20] Only petitioners' *lawyers* were critical of Dr. Teitelbaum's methodology, asserting in legal memoranda that it was unscientific.[21]

Dr. Schecter.[22] Arnold Schecter, M.D., M.P.H., likewise enjoys "a national reputation." App. 8a. He has been a tenured medical professor since 1979 and is one of the few American physicians who works full time doing research on the toxic effects of PCBs, furans and dioxins. J.A. 399. He has published over 100 peer-reviewed papers on this subject since 1981. J.A. 399, 424-42. Although Schecter concentrates almost entirely on research and teaching, he also sees patients and has served as a consultant to the EPA, the U.S. Public Health Service, the National Academy of

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and was "not really" "aware of his opinions." S.A. 59 (Waddell). Further, even after Joiner filed, with his opposition to the summary judgment motion, an affidavit by Teitelbaum laying out his methodology in greater detail, petitioners still made no effort to impeach the validity of Teitelbaum's methodology, or of its application, with additional testimony from their own experts.

[20] *See* S.A. 54-56 (Bailey) (relying on a review of Joiner's deposition and medical records, and of scientific literature); Deposition of William J. Waddell, M.D., at 12, 14-15, 17, 24-25, 30-33, 54-55, 80-81, 100, 105-06 (same); Deposition of Dr. Philip Cole, at 8, 11, 15, 94-95] (same). See also note 57, *infra*.

[21] Those lay criticisms are repeated in this Court. For example, petitioners suggest that Dr. Teitelbaum's opinion hinged on the two mouse studies by Anderson, et al. that were singled out for criticism by the district court. Pet. Br. 9; *see also* App. 58a-61a. In fact, when asked by petitioners in his deposition on what studies he based his conclusion, Teitelbaum stated that he relied on "volumes of articles on PCBs that I've collected and read over the years." S.A. 5. As Exhibit 12-A to his deposition, Teitelbaum included a list of twenty-two studies that were particularly important (and also included photocopies of the articles, *see* Exhibit 12-C), at least four of which reviewed data on humans. *See* S.A. 3, 23-26.

[22] Teitelbaum and Schecter reached their conclusions independently of each other. S.A. 5 (Teitelbaum); S.A. 28 (Schecter).

Sciences, and the World Health Organization with respect to their study of PCBs, furans and dioxins. J.A. 399-401, 414-15; *see also* S.A. 126-27.

In reaching an opinion with respect to whether petitioners' products contributed to Joiner's development of lung cancer at age 37, Schecter testified, without contradiction, that he "followed the methodology usually and generally followed by physicians and scientists." J.A. 403. Applying this methodology, he interviewed Joiner and analyzed each of the following: Joiner's deposition testimony and affidavit; Joiner's medical records; a videotape of the conditions under which Joiner worked while repairing electrical transformers containing petitioners' products; the results of PCB testing done on these transformers; the relevant available scientific literature on the toxic effects of the PCBs, furans and dioxins contained in petitioners' products; the scientific literature demonstrating that these substances tend to accumulate in the lung, the target organ here; and the deposition testimony of the other experts in the case. Applying this methodology, Schecter eliminated other potential causes of the early onset of Joiner's lung cancer based on biographical data showing that Joiner had not been exposed to other substances known to promote the development of initiated cancer cells. J.A. 403-07; S.A. 33-34, 36.

Based on his analysis, Dr. Schecter concluded that it was likely that "Robert Joiner's exposure to PCB contaminated mineral oil dielectric fluid served as a promotional effect on his lung cancer cells, probably initiated by cigarette exposure years before and caused him to contract lung cancer at the very young age of 37. But for Robert Joiner's exposure to PCB contaminated mineral oil dielectric fluid I believe that he would not now be suffering from lung cancer." J.A. 403.

None of petitioners' experts disagreed with any aspect of Schecter's methodology, or with his application of the methodology, or with the types of data that he relied upon.[23]

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[23] Petitioners' experts perfunctorily mentioned having read Schecter's deposition, S.A. 55 (Bailey); S.A. 59 (Waddell); S.A. 61 (Cole); and/or limited their criticisms to Schecter's "opinions" or "interpretations of the analytical data."

Instead, petitioners' experts simply used this same basic methodology to reach opposite conclusions. See note 20, *supra*. Only petitioners' *lawyers* were critical of Dr. Schecter's methodology, asserting that it was unscientific.[24]

D. The Motion for Summary Judgment

Petitioners moved for summary judgment on two basic grounds. First, they claimed that the testimony of Drs. Teitelbaum and Schecter was inadmissible under Fed. R. Evid. 702 because these experts had assumed that Joiner was exposed to furans and dioxin when, in fact, the record did not support that assumption.[25]

S.A. 59 (Waddell); S.A. 74 (Brown). Indeed, one of petitioners' experts, when asked if he had "an opinion as to the[] scientific validity" of Schecter's publications on the subject of PCBs, testified that "I think the data is probably about as good as could be obtained," that Schecter has "worked with a lot of analytical chemists that are well regarded," and that he could not "think of any specific cases where" he disagreed with Schecter's analysis. S.A. 65-66 (Hamilton).

[24] Those lay criticisms are repeated in this Court. As with Dr. Teitelbaum, *see* note 21, *supra*, petitioners claim that Schecter's testimony hinged on the same two mouse studies by Anderson, et al. on which the district court focused its attention. Pet. 5-6 (citing J.A. 110-11). But the cited pages do not support the contention that Schecter relied in any way on these particular studies; instead, Schecter states that in evaluating the promotional effects of PCBs, furans and dioxins, he relied on a number of human and animal studies. J.A. 110-11. Petitioners' experts agreed that it is an entirely appropriate methodology to take into account animal studies with respect to this issue. *See, e.g.*, S.A. 57-58 (Waddell) (animal studies are necessary "because it's unethical to do to humans" what is done to the animals); S.A. 58-59 (Waddell) ("the purpose of studies on animals is to be able to get information which can or may be extrapolated in humans" and "[t]he method is accepted . . . and is appropriate and proper").

Petitioners further suggest that Schecter inappropriately ignored a test result that purported to show that Joiner received only an average dose of PCBs. Pet. Br. 6. But Schecter filed an affidavit on this subject establishing that because of methodological flaws with that test, no reasonable scientist could rely on such a test to estimate Joiner's level of exposure. J.A. 407-08. Subsequent to the filing of this affidavit, petitioners made no effort to strike this portion of the affidavit as inadmissible or otherwise to controvert the affidavit.

[25] Defendants' Joint Memorandum in Support of Summary Judgment ("SJ Memo"), filed Dec. 8, 1993, at 23-25.

Second, petitioners claimed that although Joiner was concededly exposed to PCBs, there was no evidence that he had absorbed a significant dose[26] and, in any event, that the opinions of Teitelbaum and Schecter were not "credible"[27] because several of the epidemiological and animal studies that they had looked at assertedly did not support the conclusion that petitioners' products had probably contributed to Joiner's development of lung cancer.[28] Because petitioners' experts had not offered any criticism of the methodology used by Teitelbaum and Schecter, petitioners were forced to rely on a description and critique of several of the studies offered by petitioners' lawyers.[29] Offering their own analysis of the underlying scientific data, the lawyers asserted that the conclusions reached by Teitelbaum and Schecter "are not based on credible scientific evidence and are therefore 'speculative'."[30]

In response, Joiner filed a detailed affidavit by Teitelbaum, the bulk of which explicitly rebutted the assertions of petitioners' lawyers, J.A. 456-70, and an affidavit by Schecter setting out his methodology and conclusions in more detail. J.A. 403-10. Even at this juncture, petitioners filed no expert testimony in support of their lawyers' assertions; nor did petitioners file a motion *in limine* to rule inadmissible anything in the affidavits. Instead, they simply filed another memorandum of *law* making further assertions that the conclusions reached by Joiner's experts were incorrect.[31]

E. The District Court's Grant of Summary Judgment

Three separate rulings of the district court are relevant at this juncture, as is an understanding of what the court *did not* hold:

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[26] *Id.* at 25-28.

[27] *Id.* at 10.

[28] *Id.* at 29-38.

[29] *Id.* at 29-32, 36-37.

[30] *Id.* at 3.

[31] Reply Memorandum filed February 28, 1994, at 7-11, 17-18.

1. What the District Court Held. First, the district court agreed with petitioners that there was no evidence in the record that Joiner was exposed to furans or dioxins. App. 44a-51a.

Second, building on this ruling, the district court held that "the opinions of [Joiner's] experts do not fit the facts of the case because the opinions are inextricably bound up with the experts' assumptions that Joiner was exposed to furans and dioxins." App. 53a; *see also* App. 57a (opining that Joiner "failed to show a genuine dispute over whether furans and dioxins were in the PCBs to which Joiner was exposed" so that his experts' testimony "manifestly does not fit the facts of this case, and is therefore inadmissible" under Fed. R. Evid. 702). This, the district court stated, was the "strongest" argument for refusing to admit the experts' causation testimony. App. 53a.

Third, and finally, the district court held that even if Joiner's experts "had not made unfounded assumptions about furans and dioxins," App. 58a, but instead had predicated their opinions solely on the theory that PCBs alone had promoted the development of Joiner's lung cancer:

> Defendants still persuade the court that Plaintiffs' expert testimony would not be admissible. Defendants do this by attacking the conclusions that Plaintiffs' experts draw from the studies they cite.

App. 58a. After agreeing with the analysis in petitioners' memoranda of law concerning the proper conclusions to be drawn from several of the studies considered by Joiner's experts, *see* App. 58a-67a, the district court held that it was "persuaded" that "the studies simply do not support the experts' position that PCBs *more probably than not* promoted Joiner's lung cancer." App. 67a (emphasis in original).

2. What the District Court Did Not Hold. Because the district court's rulings were predicated on its initial finding that there was no evidence in the record that Joiner was exposed to furans or dioxins, App. 44a-51a, the district court never addressed — one way or the other — the issue of whether the testimony of Joiners'

experts that PCBs, furans and/or dioxins, *in combination*, had promoted Joiner's lung cancer, was admissible. In other words, the district court did not hold that the experts' *actual* testimony was inadmissible under *Daubert* if, as the experts assumed, Joiner was exposed to all three substances. The district court simply regarded that testimony irrelevant, based on its initial holding that there was no evidence that Joiner was exposed to furans or dioxins. It only ruled inadmissible what Joiner's experts might *hypothetically* have testified to in light of its first ruling: that PCBs *alone* promoted Joiner's lung cancer.[32]

F. The Court of Appeals' Rulings in Reversing the District Court's Grant of Summary Judgment

Since the parties' briefs were in agreement on the applicable standard of review of summary judgment rulings involving the admissibility of expert testimony,[33] the standard of review was only

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[32] That point is made unambiguously clear by the district court's statement that one reason the "Yusho study" had "no utility for Plaintiffs' purposes" is that "the persons studied were exposed to furans and dioxins." App. 67a. Thus, the Solicitor General's suggestion that this Court could reverse the court of appeals and direct it to affirm the district court's grant of summary judgment, *see* SG Br. 24-30, suffers from a basic conceptual error: given the court of appeals' holding — uncontested in this Court — that the record does contain evidence of exposure to furans and dioxins, see pp. 16, 21, 31-33, *infra*, and the absence of any ruling by the district court that the expert testimony respecting the causative impact of the three carcinogenic substances in combination is inadmissible, there is nothing left to affirm. Not surprisingly, therefore, petitioners themselves seek only a remand of the case for further proceedings, *see* Pet. 14 n.4, and argue not that the district court's judgment must be affirmed, but only that "the judgment of the Court of Appeals should be reversed." Pet. Br. 50.

[33] *See* Brief of Appellants, No. 94-9131, 11th Cir., at 4-5; Brief of Appellees at 8-9 & n.9. *See also* Reply Brief of Appellants at 6 n.3 (noting parties' agreement "that if a district court uses a proper construction of the Federal Rules of Evidence in ruling on admissibility issues, its rulings are subject to abuse-of-discretion review" and that defendants did not contest the analysis in Joiner's opening brief that "*de novo* review applies in determining whether the district court applied an erroneous construction of the Federal Rule of Evidence" and that "abuse-of-discretion review is conducted more strictly, and with greater scrutiny, where necessary to ensure that the district court does not substitute its judgment for that of a jury.").

briefly discussed at the beginning of the court of appeals' opinion. App. 4a-5a.[34] The court of appeals reversed the district court on the following grounds:

1. The District Court's Assertion of the Absence of Exposure to Furans and Dioxins, and the Consequent Lack of "Fit"

With respect to the district court's first ruling, the Eleventh Circuit held, on the basis of its review of the record, that "a genuine dispute . . . exists over whether furans and dioxins could have been present in the dielectric fluid." App. 14a-15a. Based on its reversal of the first ruling, which was the sole predicate of the district court's second ruling concerning a lack of "fit," the Eleventh Circuit then held that "the testimony of plaintiffs' experts was erroneously excluded and summary judgment should not have been granted." App. 16a.[35]

[34] The standard of review was set out in the opinion of Judge Barkett, and the special concurrence of Judge Birch fully accepted this analysis. App. 16a-17a. Judge Smith, in his opinion dissenting on other grounds, also accepted Judge Barkett's analysis, although he endeavored to set forth "a more precise explanation of the standard of review," using somewhat different "review terminology." App. 18a-19a.

[35] As with the standard of review, the grounds for reversing the district court's first and second rulings were set forth in Judge Barkett's opinion, and Judge Birch's special concurrence did not disagree with this analysis in any respect. *See* App. 16a-17a. Judge Smith, in dissent, indicated that he would uphold the district court's first ruling (and, on that basis, the second ruling as well). He conceded that there *was* record evidence of exposure to furans and dioxins, but would have upheld the district court because (he thought) plaintiffs had not adequately called that evidence to the attention of the district court. *See* App. 22a-23a. Petitioners did not seek certiorari with respect to the majority's decision that there is a genuine issue of material fact as to whether Joiner was exposed to furans and dioxins.

2. The District Court's Holding That, Even if Predicated Solely on Exposure to PCBs, the Conclusions of Joiner's Experts Were Not Supported by the Studies They Cited

Addressing the district court's analysis of whether the expert opinions were admissible if based on exposure to PCBs *alone*, the Eleventh Circuit held that the district court had erred as a matter of law in its construction of Fed. R. Evid. 702.[36] After noting that the testimony of Joiner's experts — that they had "each utilized scientifically reliable methods and procedures in gathering and assimilating all of the relevant information in forming their respective opinions" — was *uncontroverted* by any testimony from scientists, App. 10a-11a, and that the district court had declared only that the experts' "conclusions" were unreliable, the Eleventh Circuit held that the district court had committed the very legal error against which this Court had cautioned in *Daubert*:

> "The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."

App. 13a (quoting *Daubert*, 509 U.S. at 595).[37]

G. The Petition for Rehearing and Petition for Certiorari

Following the reversal of all three of the district court's rulings, petitioners filed a petition for rehearing. Petitioners did not seek

[36] The Eleventh Circuit did not explain why it addressed this issue, given that its first ruling alone required reversal. Perhaps it reasoned that the issue might recur at a later stage of the litigation (e.g., if petitioners asked the district court to instruct the jury that if it found no exposure to furans and dioxins, then it must rule for petitioners). In this respect, the Eleventh Circuit observed that "it does not necessarily follow that each expert's opinion that PCB caused Joiner's cancer was contingent upon his exposure to furans or dioxins," so that it could be regarded as "immaterial whether there were furans and dioxins in the fluid." App. 14a.

[37] The court of appeals went on to hold that, in light of petitioners' failure to introduce any expert testimony challenging the reliability of the methodology of Joiner's experts, "PCB exposure only" expert testimony would be admissible, creating "a genuine factual dispute as to whether PCBs alone can cause cancer," and making this issue "inappropriate for summary judgment." App. 14a.

rehearing on the panel's fact-specific analysis of the district court's first two rulings. They did seek rehearing on the panel's decision on the third ruling, arguing that the panel had too narrowly construed the scope of a district court's "gatekeeping" authority under *Daubert*.[38] Further, petitioners objected to a portion of the court of appeals' description in its opinion of the standard of review for admissibility rulings.[39] Rehearing was denied without dissent. App. 32a-33a.

Subsequently, petitioners sought and obtained an extended stay of the issuance of the mandate based on the argument that "[a] petition for certiorari would present a substantial question for the Supreme Court, that is, there is a conflict among the circuits as to whether the 'particularly stringent' standard of review should apply to district court *Daubert* rulings."[40] In this filing, petitioners made no suggestion that their *other* rehearing issue, concerning the panel's Rule 702 reversal of the district court for excluding testimony based on its determination that the experts' *conclusions* were unreliable, might merit review in this Court. They omitted that question from their petition for certiorari and presented only their objection to the panel's standard of review. Pet. i. "Once the proper standard of review is decided," petitioners assured this Court, the case could simply be remanded, so that this Court "need not itself reexamine the record." Pet. 14 n.4.

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[38] Suggestion of Rehearing En Banc of Appellees, No. 94-9131, 11th Cir., at 8-15. The argument made in this portion of the petition for rehearing parallels the argument that petitioners now seek to have this Court address. *See* Pet. Br. 45-50.

[39] Suggestion of Rehearing En Banc of Appellees at 4-8.

[40] Defendants-Appellees' Motion to Extend Stay of Issuance of Mandate, No. 94-9131, 11th Cir., at 1-2.

SUMMARY OF ARGUMENT

In view of the precise holdings of the district court and the grounds for reversal by the court of appeals, the issues discussed by petitioners should be resolved as follows.

I. The court of appeals correctly described the appropriate standard of review at the outset of its opinion: *de novo* review of whether, on this record, a genuine issue of material fact existed regarding Joiner's exposure to furans and/or dioxins; plenary review of whether the district court erred in its construction of a Federal Rule of Evidence; and, if the district court's ruling was free of legal error, abuse-of-discretion review of the ultimate decision respecting admissibility — with a "hard look" to see if an abuse of discretion has occurred in cases where the ruling determines whether the case will be summarily taken from the trier of fact. As we show in Part II of our argument, the last aspect of the standard of review (respecting abuse of discretion) was never reached in deciding this case, because the district court's rulings all were reversed for errors of law. Thus, the question presented in this case relates to a dictum in the opinion below. Nevertheless, as the Court has granted certiorari to review that dictum, we explain why it should be upheld. Properly understood, the "hard look" dictum does not prescribe a different standard of review, but merely expresses a commonsense approach to the allocation of scarce judicial resources: that in applying the *same* standard of review, courts will look more closely at challenged rulings that are outcome determinative and, therefore, prejudicial if erroneous.

II. Even if this Court does not agree with the "hard look" dictum, the judgment below should still be affirmed, because the dictum was not applied in this case and did not affect the disposition below. The decisive ruling in this case related to the district court's conclusion, under Rule 56 of the Federal Rules of Civil Procedure, that no record evidence existed to support the assumption of Joiner's experts that Joiner was exposed to furans and dioxins. Once the court of appeals reversed that threshold ruling — which dealt with a factbound question of the application of Rule 56 that is not before this Court on the present petition —

the district court's subsidiary rulings as to the admissibility of expert testimony under Rule 702 became unavailable as grounds for upholding the district court.

The second ruling of the court below — that, with respect to *hypothetical* testimony from Joiner's experts that exposure to PCBs alone caused his lung cancer, the district court erred as a matter of law in its construction of Rule 702 by testing for reliability of the experts' conclusions rather than their methodology — applied the plenary standard of review for error of law. District courts do not have "discretion" to misinterpret the Federal Rules of Evidence. As petitioners did not seek certiorari to review the court of appeals' legal ruling construing Rule 702, that ruling remains in place.

III. If this Court decides to consider petitioners' challenge to the legal correctness of the distinction between methodology and conclusion that the court of appeals observed — despite the absence of a question presented on this point — it will discover that petitioners' argument rests on a series of mistaken assertions about the Eleventh Circuit's analysis and the record in this case, as well as a failure to recognize that the very claim petitioners assert here was advanced in *Daubert* and rejected by this Court.

ARGUMENT

I. THE JUDGMENT BELOW SHOULD BE AFFIRMED BECAUSE THE DECISION OF THE ELEVENTH CIRCUIT WAS CORRECT IN ITS DESCRIPTION OF THE APPROPRIATE STANDARD OF REVIEW

As explained in Part II of this brief, the court of appeals never engaged in abuse-of-discretion review of the district court rulings as to the admissibility of expert testimony. Instead, the district court was reversed for legal error, both on the issue of exposure to furans and dioxins and on the independent issue of the proper construction of Rule 702. Abuse-of-discretion review was mentioned only when the court began its opinion (as appellate courts often do) by reciting the review standards that govern in the particular area. App. 4a-5a; see also pp. 15-16 & nn. 33 and 34,

supra. Thus, the question presented in this Court pertains to a dictum in the opinion below. Nonetheless, we begin by showing that the Eleventh Circuit's recital of the review standards in this area was correct.

A. The Eleventh Circuit Correctly Reviewed the Record *De Novo* to Determine If a Genuine Issue of Material Fact Existed With Respect to Exposure to Furans and Dioxins

Citing this Court's decision in *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986), the court of appeals first stated that a grant of summary judgment is reviewed *de novo*; that "[s]ummary judgment is appropriate when there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law" under Fed. R. Civ. P. 56(c); and that "[t]he moving party bears the burden of showing that there is no issue of material fact." App. 4a. Petitioners do not challenge this standard. As the *amicus* brief filed by the Solicitor General ("SG Br.") recognizes, this standard of review was proper. SG Br. 24.

The court of appeals applied this standard to the district court's holding (see p. 16, *supra*) that on this record there was no genuine issue of material fact as to whether Joiner was exposed to furans and dioxins. Under this standard, the court of appeals conducted its own *de novo* review of the record and determined that there *was* a triable issue of exposure to furans and dioxins.

This ruling — which petitioners do not challenge here — necessarily disposed as well of the district court's second ruling that because furans and dioxins were not present, the experts' testimony about the causative effect of PCBs *in combination* with furans and dioxins does not "fit" the case and on that ground is inadmissible. App. 14a-16a.

B. The Eleventh Circuit Correctly Engaged in Plenary Review of Whether the District Court Erred in Its Construction of a Federal Rule of Evidence

In its summary of the standard of review, the court of appeals stated that "[t]o the extent that the district court's ruling turns on an interpretation of a Federal Rule of Evidence, our review is plenary."

App. 5a (citing *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 749 (3d Cir. 1994)). This analysis, which petitioners do not challenge, was obviously correct under this Court's past rulings. *See, e.g., Daubert*, 509 U.S. at 587 ("We interpret the legislatively-enacted Federal Rules of Evidence as we would any statute."); *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 (1988) ("Because the Federal Rules of Evidence are a legislative enactment, we turn to the 'traditional tools of statutory construction' in order to construe their provisions.") (citation omitted). .

The court of appeals then proceeded to engage in plenary review of the construction of Rule 702 relied on by the district court when it held that if, hypothetically, Joiner's experts had assumed exposure to PCBs alone, testimony of probable causation would not be admissible. The district court had based its ruling on the fact that it was "persuade[d]" by petitioners' attack on "the conclusions that Plaintiffs' experts draw from the studies they cite," App. 58a — that "the studies simply do not support the experts' position that PCBs *more probably than not* promoted Joiner's lung cancer." App. 67a (emphasis in original). The Eleventh Circuit reversed on the ground that Rule 702 did not authorize the district court to address such matters. It noted that under Rule 702, as construed in *Daubert*, "the district court's focus is a narrow one and does not encompass deciding which expert's conclusions are better reasoned or more appealing," or making "independent scientific judgments on the basis of individual studies." App. 11a. The court of appeals quoted this critical passage in the *Daubert* opinion:

> "The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."

App. 13a (quoting *Daubert*, 509 U.S. at 595).

Following an analysis of the district court's opinion, *see* App. 11a-13a, the court of appeals stated:

> Instead of viewing the bases of an expert's opinion as a whole to screen out mere speculation, the district court assessed only a portion of the studies relied upon by each of the Joiners' experts, and then *excluded the testimony because it drew different conclusions from the research* than did each of the experts. Ultimately, the court should satisfy itself as to the legal reliability of proffered expert testimony, leaving the jury to decide the correctness of competing expert opinions.

App. 13a (emphasis added). Thus, the Eleventh Circuit's holding on this ground was predicated on its finding that the district court had made a basic legal error: it focused on the experts' conclusions, not on their methodology.[41] As Judge Birch amplified in his concurring opinion, the District Court failed to understand that "[t]he *sufficiency* of the evidence and the *weight* of the evidence . . . are beyond the scope of the *Daubert* analysis. Whether the conclusions advanced from the stated premises in fact follow and the persuasiveness of these conclusions in the ultimate resolution of competing opinions, are questions appropriately left to the finder of fact." App. 16a-17a.

Once the court of appeals had held that the district court erred under *Daubert* in focusing not on whether the *methodology* used by Joiner's experts was valid, but instead on whether their *conclusions* were correct, at minimum a remand on the issue for further analysis under the proper legal standard was necessary. Joiner, however, had urged the court to go further, arguing that there was "no need for a remand" given that Joiner's experts were "concededly qualified and concededly employed a valid, indeed standard, methodology."[42] After concluding, on a review of the record, that

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[41] The district court's holding, to which this ruling applied, bears recalling:

> Assuming that Plaintiffs' experts had not made unfounded assumptions about furans and dioxins, Defendants still persuade the court that Plaintiffs' expert testimony would not be admissible. Defendants do this by attacking the conclusions that Plaintiffs' experts draw from the studies they cite.

App. 58a.

[42] Brief of Appellants, No. 94-9131, 11th Cir., at 6. *See also id.* at 21 (arguing that because petitioners "submitted no expert testimony responding" to the affidavits filed by Joiner's experts, "[t]he qualifications of, and methodologies employed by, Drs. Teitelbaum and Schecter remained unchallenged. As a matter of law, the district court erred in holding their

these concessions had in fact been made by petitioners, *see* App. 8a, 10a-11a, the court of appeals ruled that "PCB exposure only" expert testimony would be admissible, creating "a genuine factual dispute as to whether PCBs alone can cause cancer" and making this issue, as well, "inappropriate for summary judgment." App. 14a.

C. Although Not Pertinent To Any of Its Rulings, the Eleventh Circuit Was Correct That, in Reviewing District Court Evidentiary Rulings Made Under a Proper Construction of the Federal Rules of Evidence, a District Court Should Be Reversed Only for an Abuse of Discretion

The court of appeals further observed, in its introductory discussion of the standard of review, that "[a] district court's ruling on the admissibility of evidence is reviewed for abuse of discretion." App. 4a. More precisely, given the prior point, if the district court does not commit an error of law in construing the relevant Federal Rule of Evidence, *then* its ruling is reviewed for abuse of discretion.[43]

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testimony inadmissible."); Reply Brief of Appellants at 10-13 (summarizing petitioners' concessions on methodology issue).

[43] Because the discussion in the court of appeals' decision of the abuse-of-discretion standard of review was a dictum that it never actually *applied* in deciding this case, it is difficult be certain what the court below *meant* by the dictum. Further, because the court's mention of this review standard was never applied to a concrete record, anything that this Court says in this case about the scope of a district court's discretion and the standard of review thereof will necessarily be abstract and hypothetical, carrying all the risks generally associated with advisory opinions. Compare *Koon v. United States*, 116 S. Ct. 2035, 2043 (1996); *First Options of Chicago, Inc. v. Kaplan*, 514 U.S. 938, 115 S. Ct. 1920, 1922-23 (1995), in both of which the court of appeals had actually applied the standard of review that was examined by this Court. In that context, we wish to flag for the Court's attention three matters that are not posed by resolution of this case but that might otherwise *inadvertently* be resolved in a general discussion of the scope of discretion accorded district courts.

First, in its *Daubert* decision, this Court stated that "[m]any factors will bear on the inquiry" into whether an expert has followed the scientific method, but did "not presume to set out a definitive checklist or test," and emphasized that "[t]he

The petition for certiorari contended that the circuits were "completely split" the issue of whether evidentiary rulings are

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inquiry envisioned by Rule 702 is . . . a flexible one." 509 U.S. at 593-94. Petitioners and their *amici* understand this to mean that district courts are free to do essentially whatever they want, free of appellate oversight, in selecting the factors that they will deploy on a case-by-case basis to judge the scientific method. Although this case does not present the issue, we understand the Court to have meant something quite different: that given the enormous range of scientific disciplines that are the subject of federal litigation and hence are governed by *Daubert*, what constitutes "good science" may vary between fields, requiring the application of different criteria in different fields. What factors may, must, or must not be applied in judging the validity of a scientific methodology in a given field would appear to involve issues of law that will ultimately be defined by the appellate courts, subject in turn to abuse-of-discretion review in the application of those factors. *See, e.g., Koon*, 116 S. Ct. at 2047. For example, if a district court chose to determine the admissibility of psychiatric testimony by using only the four factors specifically mentioned by this Court in *Daubert*, and no others, it might well conclude that all such testimony is inadmissible in all cases. (It would appear that the reliability of psychiatric testimony is not "falsifiable," nor does it have a quantifiable "error rate".) Appellate courts presumably must have authority to declare that consideration of such factors is not permissible in determining whether an expert's methodology is scientific in the field of psychiatry.

Second, as the Solicitor General briefly touches on (SG Br. 19-21), appellate courts must be able, over time, to develop *categorical* rules of admission or exclusion that can define and delimit the scope of district court discretion with respect to particular methodologies that are routinely litigated and become widely accepted as being either valid or invalid. At least some role in this area on the part of appellate courts seems essential to ensuring a basic level of consistency (rather than randomness) in the administration of justice in like cases.

Third, even where there may *not* exist a consensus built up through experience with respect to the validity of a particular methodology, there may be instances in which the methodology arises so frequently in federal litigation that it is imperative that a uniform answer as to its admissibility be declared. Imagine, for example, that half of the district judges nationwide are ruling that a particular new forensic technique that is often outcome determinative is sufficiently reliable to be admissible, while the rest of the judges are routinely excluding all evidence based on the technique. It would be intolerable to have the fate of vast numbers of cases turn entirely on the identity of the judges to whom they are assigned, without the opportunity for appellate reconciliation.

Our discussion in text addresses the reviewability of exercises of discretion that do not implicate any of the foregoing considerations.

properly reviewed for "abuse of discretion" as opposed to "manifest error." Pet. 6-10. Following the grant of certiorari, petitioners now accept the view set forth in Joiner's opposition to certiorari (at 8-13) that *all* circuits apply an abuse-of-discretion standard, although some judges occasionally use older "manifest error" language to express precisely the same level of deference to district courts. *See* Pet. Br. 24-26.[44] The dissenting judge below agreed on the "deference to the trial court's admissibility determinations" that exists under *Daubert*, App. 20a n.1, although he also offered "a more precise explanation of the standard of review," using "terminology that is firmly established in the jurisprudence of this and other circuits." App. 18a-19a. The *amici* supporting petitioners who address the standard-of-review issue are likewise in accord. Thus, there appears to be broad agreement that the court below did not err in this dictum.

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[44] *See, e.g.*, *United States v. Rahm*, 993 F.2d 1405, 1409-10 (9th Cir. 1993) (observing that "general adoption of the 'abuse of discretion' characterization would bring this area into line with the rest of our law of evidence. . . . The 'manifest error' characterization apparently emanates from a Supreme Court decision preceding the judiciary's efforts to settle on a limited number of review characterizations. *See Salem v. United States Lines Co.*, 370 U.S. 31, 35 (1962). There appears to be no practical difference between the two verbal formulae, so their vestigial co-existence serves no obvious purpose. Accordingly, it would be sensible to settle upon a uniform practice of characterizing our standard of review as 'abuse of discretion' and abiding by it in all future cases") (citations omitted); *United States v. Boney*, 977 F.2d 624, 628 n.2 (D.C. Cir. 1992) (the two standards amount to "the same test"); *Phillips Oil Co. v. OKC Corp.*, 812 F.2d 265, 280 & n.32 (5th Cir.), *cert. denied*, 484 U.S. 851 (1987) ("We construe these various statements of the standard of review to be harmonious.").

Even if "manifest error" were a different standard, petitioners and their *amici* agree that "abuse of discretion" — the standard recited by the court of appeals below — is the correct one.

D. Although Not Pertinent to Any of Its Rulings in This Case, the Eleventh Circuit Was Also Correct in Endorsing the Third Circuit's Practice of Taking a "Hard Look" at Whether a District Court Has Abused Its Discretion in Rulings Excluding Expert Testimony Where the Rulings May Entirely Preclude the Trier of Fact From Considering a Litigant's Case

Finally, in its brief overview of the proper review standard, the Eleventh Circuit endorsed the view taken in Judge Becker's *Paoli* decision that appellate judges should take a "hard look" at certain decisions relating to the exclusion of expert testimony. App. 4a-5a (citing *Paoli*, 35 F.3d at 750). Petitioners suggest that this is a new, *different* standard of review for expert testimony, and they suggest that the judges on the court below were divided on whether a "hard look" is warranted in such cases, stating that "Judge Smith in dissent reasoned that there should be 'deference to the trial court's admissibility determinations.'" Pet. Br. 16 (quoting App. 20a n.1). Petitioners are doubly wrong: this is not a different standard, and Judge Smith did not disagree with the majority on this point.

Judge Smith, in fact, clearly stated his understanding that in reviewing for abuse of discretion, the majority's requirement that appellate judges take a "hard look" in appropriate circumstances *does not* involve a different standard of review. Elaborating on the brief summary of this point by the majority, he noted: "In applying a 'particularly stringent' review, we do not change the threshold of review, but conduct a searching review of the record (i.e., take a 'hard look') while maintaining the proper standard of review." App. 18a (citing *Paoli*, 35 F.3d at 749-50). Indeed, in the very footnote quoted by petitioners, in which Judge Smith cited case law from "circuits addressing *Daubert* [that] have shown similar deference to the trial court's admissibility determinations," Judge Smith cited the *Paoli* case itself, approvingly, as embodying such deference. He described *Paoli* as involving simply "a 'hard look' at trial court's exercising its discretion." App. 20a-21a n.1.

Our reading of the decision below with respect to the standard of review is simply that, in a world of limited judicial resources, appellate courts will devote more time and attention — i.e., a "hard look" — to determining *whether* a district court has abused its discretion in admissibility rulings that are outcome determinative of

the case. So construed, Judge Becker's analysis, and its endorsement by the court of appeals below, is hardly objectionable. It flows from the commonsense perspective that appellate judges should spend their time on the cases where there is the greatest danger that an abuse of discretion has occurred: e.g., in a case where a trial judge's discretionary decision on admissibility has determined the outcome of the entire litigation, not in a case where the evidence excluded was cumulative.

Obviously, it makes little sense for appellate judges to take the time to engage in a hard look at the record of a case with respect to rulings where the asserted error had little to do with the outcome of the case. As the *Paoli* decision observed, "the likelihood of finding an abuse of discretion is affected by the importance of the district court's decision to the outcome of the case and the effect it will have on important rights." *Id.* at 750. This analysis was supported by reference to the doctrine permitting reversal only for prejudicial error, and by analogy to this Court's decision in *Mathews v. Eldridge*, 424 U.S. 319, 334 (1976), recognizing that "the procedural safeguards required by due process increase as the importance of the decision being made increases." *Paoli*, 35 F.3d at 750.[45] Of course, as Judge Smith observed below, devoting extra resources to determining whether an abuse of discretion has occurred on a given record does not *change* the standard of review.

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[45] From this perspective, Judge Becker's statement that a "hard look" should be accorded only in cases where the admissibility ruling is outcome determinative is nothing more than a "concession to the shortness of life." *Reeve v. Dennett*, 11 N.E. 938, 944 (1887) (Holmes, J.). In a world of unlimited resources, all appellate judges would: (1) take a hard look at each and every evidentiary ruling on which error is asserted, determining whether an abuse of discretion has occurred, and then (2) apply the doctrine of prejudicial error to determine whether the disadvantaged party is entitled to relief. As petitioners themselves recognize, Pet. Br. 39-40, we do not live in such a world. It is eminently rational for appellate judges to devote less time to the review of admissibility decisions that are unlikely to have had much to do with the outcome of the case, thereby conserving scarce time and energy for the review of important admissibility rulings. Thus, viewed in context, the "hard look" is merely a doctrine permitting the efficient allocation of judicial resources.

The concept of reserving extra judicial time and attention for important admissibility decisions, and less time for trivial ones, need not inevitably cut in favor of the admission of evidence. As one *amicus* brief filed in support of petitioners observes, "[i]n suggesting that 'a hard look' should be taken, appellate courts have expressed their concern about trial court decisions *to admit or exclude*."[46] As this *amicus* brief points out, in a leading decision written by Judge Higginbotham, the Fifth Circuit has noted that although it "adhere[s] to the deferential standard for review of decisions regarding the admission of testimony by experts," appellate judges "will turn to [their review] task with a sharp eye, particularly in those instances, hopefully few, where the record makes it evident that the decision to receive expert testimony was simply tossed off to the jury under a 'let it all in' philosophy." *In re Air Crash Disaster Near New Orleans*, 795 F.2d 1230, 1234 (5th Cir. 1986). This approach has been followed in other circuits as well.[47]

Whether one speaks of a "hard look" or of a "sharp eye," the message is the same: without applying a *different* standard of review, and within the accepted context of reviewing evidentiary rulings for abuse of discretion, appellate judges may reasonably reserve the bulk of their time and attention for evidentiary issues that matter to the outcome of litigation, whether those issues involve the exclusion of evidence (addressed by *Paoli*) or the admission of evidence (addressed by *In re Air Crash Disaster*). Upholding the use of Judge Becker's "hard look" at whether an abuse of discretion has occurred, where the result of a ruling excluding evidence is important because it is the basis for a grant of summary judgment against a plaintiff, does *not* constitute a rejection of Judge Higginbotham's concern for an equally hard look by appellate courts with respect to potentially outcome

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[46] Brief of *Amici Curiae*, The Product Liability Advisory Council, Inc., The National Association of Manufacturers, and Medmarc, in Support of Petitioners ("PLAC Br.") at 7 (emphasis added).

[47] *See Joy v. Bell Helicopter Textron, Inc.*, 999 F.2d 549, 569-70 (D.C. Cir. 1993); *United States v. DiDomenico*, 985 F.2d 1159, 1163 (2d Cir. 1993).

determinative rulings in favor of the admissibility of evidence (where, but for the admissibility ruling, a grant of summary judgment in favor of defendant might be warranted). Whether a comparable "hard look" for abuse of discretion is warranted in the latter circumstance is a question that can, and should, be deferred until an appropriate case is presented.[48]

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[48] There are two possible grounds for devoting greater appellate resources to reviewing the exclusion of critical evidence than its admission. The first is the preference for the admissibility of relevant evidence that Congress embedded in the plain language of the Federal Rules of Evidence. Fed. R. Evid. 402 creates a presumption that "all relevant evidence is admissible," so that it can be excluded only if "provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority." This Court has noted the "liberal thrust of the Federal Rules" and, in particular, how Rules 702 through 705 follow a "general approach of relaxing the traditional barriers to 'opinion' testimony." *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988); *see also* App. 4a (noting "preference for admissibility" underlying Federal Rules of Evidence). One of petitioners' *amici* makes a worthwhile point that Rule 402 and "the liberal policies underlying the Rules" should not be double or triple counted with respect to the standard of review. *See* Brief of the Chamber of Commerce of the United States as *Amicus Curiae* in Support of Petitioners at 26-27. Presumably, however, the explicit statutory presumption in favor of admitting relevant evidence justifies devoting at least *some* additional appellate resources to deciding whether specific rules authorize the exclusion of evidence that meets the threshold test of relevancy.

Another possible distinction between the two situations is that the exclusion of important, relevant evidence, unlike its admission, can impair the full realization of a significant constitutional value — the Seventh Amendment guarantee of a jury trial. *See, e.g., Paoli*, 35 F.3d at 750 n.20. For example, even though it is not outcome determinative of a case, appellate courts have long engaged in "a more searching inquiry" of a grant of a new trial on weight-of-the-evidence grounds than of a denial, "to protect the litigants' right to jury trial." *Langevine v. District of Columbia*, 106 F.3d 1018, 1023 (D.C. Cir. 1997) (quoting *Lind v. Schenley Indus., Inc.*, 278 F.2d 79, 90 (3d Cir.) (en banc), *cert. denied*, 364 U.S. 835 (1960)).

II. THE ELEVENTH CIRCUIT'S JUDGMENT SHOULD BE AFFIRMED EVEN IF THIS COURT DISAGREES WITH THE STANDARD OF REVIEW RESPECTING ABUSE OF DISCRETION ARTICULATED BELOW

As already noted, the court of appeals' reference to the abuse-of-discretion standard of review, and the "hard look" that at times is called for under that standard, was only a dictum that did not turn out to be relevant to the disposition of this case. The court of appeals' rulings were reached on threshold grounds — legal error by the district court — that mooted any question of abuse of discretion. It follows that even if the Court does not agree with the standard of review recited in dictum below, the judgment of the court of appeals still must be affirmed.

A. Petitioners Did Not Seek Review of the Eleventh Circuit's Holding That the Record Contains Evidence of Joiner's Exposure to Furans and Dioxins — a Holding That is Unaffected by the "Hard Look" Reference And That Is Dispositive

Affirmance of the court of appeals is required, first and foremost, because the key ruling of the district court — that there was no genuine issue of material fact concerning whether Joiner was exposed to furans and dioxins — constituted legal error. Based on this threshold legal error, the district court held that because Joiner's experts assumed exposure to furans and dioxins, their testimony did not "fit" the facts of the case, and must therefore be excluded under Rule 702. See p. 14, *supra*.

Once the Eleventh Circuit held, on *de novo* review, that the record did present a genuine issue concerning Joiner's exposure to furans and dioxins, it was required to reverse the district court's Rule 702 holding that the testimony of Joiner's experts did not "fit" the facts, because that ruling was entirely premised on an erroneous view of the record. It did so. See p. 17, *supra*.[49]

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[49] We note that, at this narrow juncture, one can describe the court of appeals' opinion as based on a finding that the district court abused its discretion — in that it is always an abuse of discretion for a district court to rule evidence

A grant of certiorari on the factbound issue of whether the court of appeals was right in its dispositive determination concerning furans and dioxins would have been highly unusual,[50] and petitioners elected not to ask this Court to review that issue. Indeed, with respect to this issue they did not even seek rehearing in the Eleventh Circuit. It is therefore clear at this juncture "that respondents have adequately raised a factual issue concerning Robert Joiner's exposure to furans and dioxins." SG Br. 24. It follows that the Eleventh Circuit's decision reversing the *only* district court ground for excluding expert testimony premised on

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inadmissible based on a clearly incorrect, and pivotal, assumption about the record facts. But petitioners do not contend that *this* holding of the court of appeals was in any way affected by the "hard look" approach endorsed by the panel of which petitioners complain. As is clear from the Solicitor General's analysis, this holding is proper under any conception of the abuse-of-discretion review standard:

> [T]he court of appeals was entitled to review for clear errors of fact or law affecting the district court's ruling. Because it reversed the trial court's holding that there was no genuine issue of fact concerning respondent's exposure to furans or dioxins, the court of appeals could properly conclude that it should also reverse the admissibility ruling to the extent that it relied on the observation that the proffered opinions were "inextricably bound up with the experts' assumption that Joiner was exposed to furans and dioxins." Pet. App. 53a; see *id.* at 53a-57a. The ruling that the proffered testimony "manifestly does not fit the facts of this case" (*id.* at 57a) was based on a view of the facts that was clearly incorrect in light of the appellate court's independent ruling on summary judgment, and it therefore cannot remain a permissible ground for exclusion under Rule 702.

SG Br. 25.

[50] *See generally* Robert L. Stern, et al., *Supreme Court Practice* § 4.14, at 189-91 (7th ed. 1993). Obtaining certiorari on this issue would have been especially difficult given the evidence from petitioners' own experts, and from Joiner's experts in testimony which petitioners did not attack as inadmissible, showing that during Joiner's relevant work period, furans and dioxins were routinely present in the commercial PCB mixtures that contaminated the mineral oil transformers with which Joiner worked. See note 4, *supra*. Petitioners' discussion ignores this evidence and focuses on asserted gaps in the record concerning the precise mechanics by which the furans and dioxins that are routinely present are generated. *See* Pet. Br. 7, 9, 13 n.13.

exposure to *a combination* of these carcinogenic substances cannot be disturbed on this record, thus requiring that the judgment of the court of appeals be affirmed.

As we have already observed, see note 32, *supra*, there is a basic conceptual error in the Solicitor General's suggestion (not advanced by petitioners) that this Court might enter a judgment affirming the district court's grant of summary judgment. Such a result would only be possible if the district court had ruled, in the alternative, that even if the testimony of Joiner's experts had *correctly* assumed exposure to PCBs, furans and dioxins, such testimony would be inadmissible because the district court was "not persuaded" that the studies on PCBs, furans and dioxins supported the particular conclusions of the experts. But the district court made no such holding and, indeed, given the concession of petitioners' experts that furans and dioxins are more carcinogenic than PCBs, see note 5, *supra*, it could hardly have done so. Instead, the district court simply held that in its view the studies *on PCBs alone* did not support the conclusions of Joiner's experts. Once the court of appeals held that the record supported a finding of Joiner's exposure to all three substances, there was simply nothing left to affirm.

B. Petitioners Did Not Seek Review of the Eleventh Circuit's Holding That the District Court Committed Legal Error in Its Construction of Rule 702 — a Holding Also Unaffected by the "Hard Look" Reference

Affirmance of the court of appeals is also required because the only holding of the district court whose reversal is challenged in this Court — that if the testimony of Joiner's experts were construed as asserting causation based on exposure to PCBs alone, it would be inadmissible under Rule 702 — was unaffected by the Eleventh Circuit's reference to a "hard look" in abuse-of-discretion review of admissibility rulings.

The court of appeals addressed the district court's third ruling (perhaps because it might eventually arise in the case, if the jury determined as a matter of fact that Joiner was *not* exposed to furans and dioxins, see note 36, *supra*). It reversed because it found an error of law: an incorrect construction of the Rule 702 reliability test articulated by this Court in *Daubert*. The district court quite

explicitly said that it was rejecting the testimony of Joiner's experts because the *conclusion* they reached was unreliable. The court of appeals understood this Court's decision in *Daubert* to have held that only the methodology, not the conclusion, is to be tested for reliability. See pp. 17, 22-23, *supra*. Thus, in the view of the court of appeals, the district court's ruling was infected by legal error. And legal error, of course, is subject to plenary review. (This is true whether or not the court of appeals was *correct* in its understanding of *Daubert*, an issue petitioners chose not to present in their petition.)

* * *

In sum, none of the rulings below turned on any review of the district court's rulings for abuse of discretion, much less a "hard look" at whether the district court abused its discretion. On that basis, the judgment of the Eleventh Circuit should be affirmed even if this Court disagrees with the abuse-of-discretion standard of review as it was articulated in dictum below.

III. PETITIONERS' CLAIM THAT THE TESTIMONY OF JOINER'S EXPERTS IS INADMISSIBLE UNDER RULE 702 IS WITHOUT MERIT

Petitioners plainly recognize that the court of appeals' last-discussed ruling was predicated on the view that there was an error of law in the district court's Rule 702 analysis. Thus, despite not having presented the question in their petition for certiorari, they now argue at the close of their merits brief that the court of appeals committed legal error of its own in its construction of Rule 702 and, in particular, misconceived the line between methodology and conclusion. *See* Pet. Br. 46-50.[51] Various *amici* representing the

[51] Citing primarily the court of appeals' discussion of whether the record contained evidence of Joiner's exposure to furans and dioxins, petitioners also complain at this juncture that "whenever it believed information relevant to admissibility was lacking," the court "put the burden of producing it on petitioners." Pet. Br. 45 (citing App. 15a, Pet. Br. 36-37). As explained earlier, petitioners' inability to convince the court of appeals that no genuine issue existed with respect to the presence of furans and dioxins involved only a garden-

interests of companies and individuals who are often named as defendants in tort litigation join petitioners in an effort to persuade this Court to collapse the methodology/conclusion distinction and empower district courts to assess the reliability of the *conclusions* reached by experts who are applying indisputably correct *methodologies* — under the guise of assessing whether there is a "logical" or "analytical" gap between methodology and conclusion. We address these belatedly asserted Rule 702 issues on the chance, however remote, that this Court might choose to reach them.[52]

variety record analysis under Rule 56, not an evidentiary issue under Rule 702. See p. 21, *supra*. Petitioners also cite here the court of appeals' observation that the district court had ruled on the basis of what various studies said without having *obtained and read the studies*. App. 13a n.9. But this observation placed no burden on petitioners; under Fed. R. Evid. 705 the burden would have been on Joiner to supply any copies (beyond the 22 studies already provided by Teitelbaum, see note 21, *supra*) had the district court requested them. *See, e.g.*, *Ambrosini v. Labarraque*, 966 F.2d 1464, 1468-69 (D.C. Cir. 1992).

[52] In their petition for certiorari, petitioners posed only the standard-of-review issue and stated that "[o]nce the proper standard of appellate review is decided, this Court need not itself reexamine the record," but could simply order that "'the case is remanded for further proceedings consistent with this opinion.'" *Id.* at 14 n.4 (quoting disposition of *Daubert*, 509 U.S. at 598). Once review was granted, however, petitioners designated 520 pages of the record below and proceeded to revive the very Rule 702 arguments on the proper scope of this Court's *Daubert* analysis that they had raised on rehearing but not in the petition for certiorari. See pp. 17-18, *supra*. *But see* Sup. Ct. R. 14.1(a) ("Only the questions set out in the petition, or fairly included therein, will be considered by the Court"). *See also Izumi v. U.S. Philips Corp.*, 510 U.S. 27, 30-32 (1993); *Yee v. City of Escondido*, 503 U.S. 519, 535-36 (1992); *Irvine v. California*, 347 U.S. 128, 129-30 (1954) (plurality opinion of Jackson, J.). *See, e.g.*, *First Options of Chicago, Inc. v. Kaplan*, 514 U.S. 938, 115 S.Ct. 1920, 1926 (1995) ("Finally, First Options argues that, even if we rule against it on the standard-of-review questions, we nonetheless should hold that the Court of Appeals erred in its ultimate conclusion that the merits of the Kaplan/First Options dispute were not arbitrable. This factbound issue is beyond the scope of the questions we agreed to review.").

A. The Eleventh Circuit Did Not Rule the Testimony of Joiner's Experts Admissible Based Merely on Their Credentials

Petitioners claim error in the court of appeals' supposed holding that Rule 702 can be satisfied by the mere fact that a party's experts are exceptionally qualified. Pet. Br. 46-47 (citing App. 11a). The court below held no such thing. In the passage cited by petitioners, the court merely noted that "the extensive experience and specialized expertise of each of these experts *augment* the reliability of their reasoning and methodology," and have "*some* bearing on the determination of the reliability of the underlying reasoning or methodology." App. 11a (emphasis added). In *Daubert*, this Court noted that "[m]any factors will bear on the inquiry" under Rule 702 into the reliability of an expert's methodology, and it did "not presume to set out a definitive checklist or test," choosing instead simply to list four illustrative factors. 509 U.S. at 592. The court below cited precedent from two other circuits taking into account an expert's exceptional qualifications as *one* factor in evaluating methodology under Rule 702, and none of the cases cited by petitioners suggests that it is legal error to do so.

More fundamentally, petitioners fail to acknowledge that consideration of the qualifications of Joiner's experts came only *after* the court of appeals had cited its primary reason for concluding that Rule 702 had been satisfied here. The uncontradicted record evidence, it noted, established that each of Joiner's experts "utilized scientifically reliable methods and procedures in gathering and assimilating all of the relevant information in forming their respective opinions," that these methods are generally accepted, and that "defendants do not challenge these claims." App. 10a-11a.

Petitioners assert that this holding is "[q]uite unaccountabl[e]," Pet. Br. 37, and claim that they introduced evidence from their experts "explicitly" challenging the methodology of Joiner's experts. Pet. Br. 38. But that simply is not the case. As Joiner

established in his briefing below without contradiction,[53] petitioners' *experts* never attacked the methodology used by Joiner's experts, see notes 19 & 23, *supra*, and they actually employed the same methodology to reach their own conclusions. See note 20, *supra*. The testimony cited by petitioners, Pet Br. 38, simply reveals that petitioners' experts reached *different conclusions* respecting causation using *the same methodology*.[54]

Of course, petitioners also cite at this juncture the fact that their lawyers made assertions in their briefs challenging the methodology of Joiner's experts. Pet. Br. 38 (citing J.A. 387-88, 390-91, 515, 517). Indeed, it was the *lawyers'* challenges that the district court professed to find persuasive. App. 58a. But "[l]egal memoranda and oral argument, in the summary-judgment context, are not evidence." *Smith v. Mack Trucks, Inc.*, 505 F.2d 1248, 1249 (9th Cir. 1974) (per curiam). There is already enough reason to worry that district judges will be tempted to play "amateur scientist" in carrying out their role under Rule 702, *see Daubert*, 509 U.S. at 600-01 (Rehnquist, C.J., joined by Stevens, J., concurring in part and dissenting in part), without deputizing lawyers to serve as

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[53] Brief of Appellants, No. 94-9131, 11th Cir., at 16-21; Reply Brief of Appellants at 13. In light of the description in these pages of the uncontradicted record evidence establishing the validity of the methodology employed by Joiner's experts, the court of appeals' observation that "defendants do not challenge these claims," App. 11a, is completely understandable.

[54] On this record, the case therefore fell under the doctrine — which had long before been adopted by the Eleventh Circuit and which petitioners do not challenge here — that where "experts on both sides rel[y] on essentially the same diagnostic methodology" and "differ[] solely on the conclusions they dr[a]w from test results and other information," an expert's testimony is to be admitted even if it is "controversial in its conclusions." *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1535 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). *See, e.g., Cella v. United States*, 998 F.2d 418, 426 (7th Cir. 1993); *Ambrosini, supra*, 966 F.2d at 1467-69; *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1111 & n. 9 (5th Cir. 1991) (en banc), *cert. denied*, 503 U.S. 912 (1992); *Hines v. Conrail*, 926 F.2d 262, 274 (3d Cir. 1991); *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 744-45 & n.8 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986). Joiner made this point to the Eleventh Circuit without contradiction from petitioners. *See* Brief of Appellants, No. 94-9131, 11th Cir., at 12.

authoritative expositors of the scientific method, whose opinions on that subject can be adopted by district courts in the face of uniform contrary testimony from professional scientists.

B. The Eleventh Circuit Did Not Err in Its Analysis That the District Court Had Committed Legal Error By Focusing Solely on the Experts' Conclusions, Not on Their Methodology

Petitioners also claim error in the court of appeals' construction of Rule 702 in that the court "treated *Daubert*'s requirement of scientific methodology at such a superficial level as to leave it meaningless — calling for no more than the invocation of scientific materials." Pet. Br. 47. The court of appeals, petitioners assert, "essentially held that if an expert cites conventional scientific authorities, the expert has satisfied the requirement of scientific methodology, no matter what the authorities actually say, and what steps are missing between the citations and the conclusion." Pet. Br. 48. If *Daubert* "made anything clear," they argue, an expert may not "escape methodological scrutiny simply by invoking a black box called science." *Id.* One answer to this argument can be found in the record; another can be found in the *Daubert* decision itself.

1. The Record

A dispositive answer to petitioners' objection, closely tied to the record of this case, is that the court of appeals did *not* find Rule 702 satisfied merely because Joiner's experts cited some scientific materials. Rather, as we have already discussed, Joiner's experts laid out in detail, both in their depositions and in Rule 56(e) affidavits answering the criticisms advanced by petitioners' lawyers, the multi-step methodology they had applied to reach a conclusion as to whether or not petitioners' products likely contributed to the development of Joiner's lung cancer at age 37. See pp. 8-12, *supra*. Reviewing this uncontroverted record evidence, the court of appeals first noted that both Dr. Teitelbaum and Dr. Schecter had conducted a standard, detailed occupational medical assessment of Joiner, analyzing his physical condition,

medical and family history, exposure to potential carcinogens, and the like. App. 9a-10a. The court then noted that "*[i]n addition*, each doctor utilized numerous scientific studies and authorities," App. 10a (emphasis added), and that "defendants [did] not challenge" the testimony of Joiner's experts that their overall methodology was scientifically valid. App. 10a-11a. Nowhere did the court of appeals remotely suggest that Rule 702 was satisfied by some abstract "invocation of scientific materials." Pet. Br. 47.

Petitioners' effort to undermine the uncontroverted record showing that Joiner's experts applied a valid methodology is unavailing. Declining to discuss *the evidence* on methodology, petitioners instead challenge the court of appeals' statement that "[o]pinions of any kind are derived from individual pieces of evidence, each of which by itself might not be conclusive, but when viewed in their entirety are the building blocks of a perfectly reasonable conclusion." App. 12a. Petitioners assert that this view is a "fallacy." Pet. Br. 49 (citation omitted).

According to petitioners' lawyers, because no epidemiological study has been performed on PCBs proving, at a "statistically significant," near-certainty level, that PCBs cause small-cell lung cancer (the precise type of lung cancer that Joiner developed), the testimony of Joiner's experts based on the body of evidence that *is* available cannot be valid. Pet. Br. 48. On this ground, petitioners would preclude reliance on the human epidemiological evidence reflecting substantial increases in cancer (including lung cancer) among those exposed to PCBs, see notes 2 & 3, *supra*, as well as the animal studies that corroborate and strengthen the implications of that evidence. See *id.* The assertions of petitioners' lawyers would require dismissing Joiner's claims despite the fact that the scientific consensus is in *his* favor, given that federal health authorities believe that it is "probable" that PCBs cause cancer in humans, including lung cancer. See note 3, *supra*.

But, contrary to the beliefs of petitioners' lawyers, the scientific method includes protocols for addressing the *likelihood* of causation in the absence of unequivocally dispositive evidence. As the EPA has observed in its official analysis of the proper methodology for deciding the likelihood that substances cause

cancer, it is rare that a carcinogen will be detected to a level of 95 percent "statistical significance" in a human epidemiological study; indeed, experts called by Joiner and petitioners alike agreed that the type of epidemiological study that petitioners erect as their ideal would be (quite conveniently for petitioners) effectively impossible to conduct.[55]

The assertion of petitioners' lawyers that the court of appeals erred in admitting the testimony of Joiners' experts because it is a "fallacy" for scientists to evaluate the full range of available data on a potential carcinogen and then reach a conclusion based on those data, using their judgment and experience, is obviously baseless. Analysis of the overall weight of available data is the very methodology used by the EPA (and its consultants, including Teitelbaum and Schecter) in assessing the likelihood of carcinogenic danger. The EPA's current guidelines on the subject state:

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[55] *See* EPA, *Guidelines for Carcinogen Risk Assessment*, 51 FED. REG. 33992, 33995-96 (Sept. 24, 1986) ("epidemiologic studies are inherently capable of detecting only comparatively large increases in the relative risk of cancer. Negative results from such studies cannot prove the absence of carcinogenic action."). *See also* Office of Science and Technology Policy, *Chemical Carcinogens: A Review of the Science and its Associated Principles*, 50 FED. REG. 10372, 10378 (1985) ("A high-quality negative epidemiological study, while useful, cannot prove the absence of an association"); S.A. 59 (Waddell) (concession by one of petitioners' experts that a controlled epidemiological study on humans that would "give them a dose" of PCBs "[t]o see whether they get lung cancer " is ruled out because it is "unethical to give anyone something to see if it produces a carcinoma . . . that's not a proper kind of experiment"); S.A. 20 (Teitelbaum) ("Q. Now, to be specific to this case, is there any study that you know of anywhere in humans that indicate that small-cell, being specific to this diagnosis, lung cancer was caused by PCBs?"; "A. No. It's an impossible research question to investigate, I think, in the first place, and in the second place, there is no such study."); S.A. 17 (Teitelbaum) ("if you wanted to study PCBs in electricians at age 35, I haven't done the calculations, but you'd need millions, I think, millions of exposed people to get a statistically significant finding, or millions of person years anyway").

> Evidence of possible carcinogenicity in humans comes primarily from two sources: long-term animal tests and epidemiologic investigations. Results from these studies are supplemented with available information from short-term tests pharmacokinetic studies, comparative metabolism studies, structure-activity relationships, and other relevant toxicologic studies. ***The question of how likely an agent is to be a human carcinogen should be answered in the framework of a weight-of-evidence judgment.*** Judgments about the weight of evidence involve considerations of the quality and adequacy of the data and the kinds and consistency of responses induced by a suspect carcinogen. There are three major steps to characterizing the weight of evidence for carcinogenicity in humans: (1) Characterization of the evidence from human studies and from animal studies individually, (2) combination of the characterizations of these two types of data into an indication of the overall weight of evidence for human carcinogenicity, and (3) evaluation of all supporting information to determine if the overall weight of evidence should be modified.

EPA, *supra* note 55, at 33996 (emphasis added).[56] It is the same methodology that was used by *petitioners'* experts.[57] Indeed, it is

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[56] Analysis of a full range of data on suspected toxins to determine their probable health effects on humans is, of course, accepted practice among a variety of federal health authorities. *See generally* Brief of *Amici Curiae* American Society of Law, Medicine and Ethics, *et al*, in Support of Petitioners, *Daubert*, No. 92-102, at 11-20 (surveying the scientific practice in this respect).

[57] As one of petitioners' experts, Dr. Bailey, put it: "I've just reviewed a lot of literature and come to some conclusions." S.A. 56. *See also* S.A. 58-59 (Waddell) ("the procedure is to get all the information we can," including animal data); S.A. 64-65 (Hamilton) (GE scientist had no expertise on PCBs before 1981; based on just one year of reviewing the literature, he had become informed enough to write a federal regulatory body arguing that it was wrong in its conclusion that PCBs are a probable human carcinogen); S.A. 62 (Cole), and Deposition of Dr. Philip Cole at 26, 88 (admits that EPA is an "august body" on the subject of "human carcinogen[s] for the lung," but simply disagrees with EPA

a fundamental part of the scientific method generally.[58]

Beyond Joiner's compelling showing on the basis of science that the assertions of petitioners' lawyers are groundless, those assertions fail the test of common sense under established principles of evidence law. It is a "simple fact[] of evidentiary life"

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that "PCB exposure is a cause of cancer in human beings"; his own conclusion is that the "body of evidence . . . doesn't give the slightest inkling that these things cause human cancer."). Of course, the fact that petitioners' experts reviewed the same data as the EPA and reached a different conclusion does not mean that their testimony is inadmissible. Such disagreement in a world of complexity and uncertainty is hardly unusual. *See, e.g.*, Laurence H. Tribe, *Trial by Mathematics: Precision and Ritual in the Legal Process*, 84 HARV. L. REV. 1329, 1348 (1971) ("Different people, of course, would typically assign different subjective probabilities to the same propositions — but that is as it must be, unless the propositions in question are unusually simple.").

[58] For example, an *amicus* brief filed in *Daubert* by a number of prominent scientists addressed this issue specifically in the context of the science of epidemiology, observing that "'[a]ll scientific work is incomplete — whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer on us a freedom to ignore the knowledge we already have, or to postpone action that it appears to demand at a given time.'" Brief *Amici Curiae* of Physicians, Scientists and Historians of Science in Support of Petitioners ("Gould Br."), *Daubert*, No. 92-102, at 9 (quoting Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 PROCEEDINGS OF THE ROYAL SOCIETY OF MEDICINE 295, 299-300 (1965)). "As a consequence," these scientists noted, "those who seek in science the immutable truth they find lacking in law are apt to be disappointed:

> One notable similarity [between law and epidemiology] is the dependence of both fields upon subjective judgments.
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> In the end, a quality which lawyers should understand better than any — judiciousness — matters more than any. Scientists use both deductive and inductive inference to sustain the momentum of a continuing process of research. . . . The courts of law, and the courts of application, use inference to reach decisions about what action to take. Those decisions often cannot rest on certitudes, most especially when population risks are converted into individual risks."

Id. at 9-10 (quoting Susser, *Rules of Inference in Epidemiology*, in 6 REGULATORY TOXICOLOGY AND PHARMACOLOGY 116, 128 (1986)).

that "individual pieces of evidence, insufficient in themselves to prove a point, may in cumulation prove it. The sum of an evidentiary presentation may be greater than its constituent parts." *Bourjaily v. United States*, 483 U.S. 171, 179-80 (1987).[59]

Moreover, to require the type of statistical certainty insisted on by petitioners would significantly alter state substantive law in the guise of applying a federal rule of evidence, without any indication from Congress of an intent to displace state law in such a sweeping manner. As Professor Nesson has observed, a "requirement that proof of causation be made exclusively according to the standards and methodology of statistical science" would be "tantamount to institutionalizing an objectively determinable probability greater than .5 for cases in which proof of causation involves a disputed supposition about the working of nature." Charles Nesson, *Agent Orange Meets the Blue Bus: Factfinding at the Frontier of Knowledge*, 66 B.U. L. REV. 521, 538-39 (1986).[60] This point has

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[59] *See also* Tribe, *supra* note 57, at 1350 ("Few categories of evidence indeed could ever be ruled admissible if each category had to stand on its own, unaided by the process of cumulating information that characterizes the way any rational person uses evidence to reach conclusions.").

[60] Of course, a State might opt for a substantive rule of law withholding compensation in the absence of "statistically significant" evidence even though, as Nesson warns, such a rule would "substantially insulate[] companies from the consequences of negligently exposing persons to toxins," giving them "an incentive to ignore even known risks" and "to use what resources and political muscle they have to obstruct or skew any epidemiological study that might prove statistically that their conduct caused injury." *Id.* at 537. Some of petitioners' *amici* apparently favor such a rule, but they make no showing either that Georgia has adopted such a rule (it has not) or that in enacting the Federal Rules of Evidence in 1975, Congress purported to change tort law in this manner. Indeed, Congress interrupted the Rules Enabling Act process and recrafted the Federal Rules of Evidence itself "to assure a *minimum* of tampering with state substantive rights," thus policing "the limitation specified in the second sentence of the 1934 Rules Enabling Act against abridging substantive rights." Olin Guy Wellborn III, *The Federal Rules of Evidence and the Application of State Law in the Federal Courts*, 55 TEX. L. REV. 371, 401 (1977) (emphasis added). *See also* 22 Charles Alan Wright & Kenneth W. Graham, *Federal Practice and Procedure: Evidence* § 5006, at 106, 108 (1978). Rule 702 would, in any event, be a particularly unlikely congressional vehicle for tort reform given that, as one of petitioners'

been made widely in the literature, by both legal scholars and scientists.[61]

2. The *Daubert* Decision

There is a further, more fundamental answer to petitioners' argument. Petitioners proceed as if this Court has never considered the issue of how much, if at all, a federal court should delve into the substance of an expert's particular conclusions in deciding whether the expert's testimony constitutes "scientific knowledge" within the meaning of Rule 702. Thus, quoting selectively from *Daubert*, petitioners state that the term "scientific knowledge" cannot involve "'subjective belief or unsupported speculation,'" Pet. Br. 47 (quoting 509 U.S. at 590), and that "'under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" Pet. Br. 48 (quoting 509 U.S. at 589). Based on these phrases, petitioners claim to find in *Daubert* the following principle: the requirement that an expert's testimony constitute "scientific knowledge" under Rule 702 "includes as a minimum that *conclusions be logically supported by premises*." Pet. Br. 48 (emphasis added). That is, the conclusions of a qualified expert witness are inadmissible under Rule 702 where a lay judge finds that "there is an 'analytic gap'" between those conclusions and the scientific materials" that is

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amici notes, "Rule 702 received little attention" in Congress. Brief of *Amicus Curiae* The Washington Legal Foundation in Support of Petitioners at 14 n.10.

[61] *See, e.g.*, Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of* Agent Orange *and Bendectin Litigation*, 86 NW. U. L. REV. 643, 667-68, 682-94, 697 (1992); V. Brannigan, V. Bier, and C. Berg, *Risk, Statistical Inference, and the Law of Evidence: The Use of Epidemiological Data in Toxic Tort Cases*, in 12 RISK ANALYSIS 343 (1992); D.H. Kaye, *Is Proof of Statistical Significance Relevant?*, 61 WASH. L. REV. 1333 (1986); Steve Gold, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 YALE L.J. 376 (1986); Neil B. Cohen, *Confidence and Probability: Burdens of Persuasion in a World of Imperfect Knowledge*, 60 N.Y.U. L. REV. 385, 413-14 (1985).

"simply 'too wide'."[62]

According to petitioners, under Rule 702 it is not enough that an expert is applying a concededly valid methodology to reach a conclusion on a disputed scientific issue. Instead, the conclusion *itself* must "be logically supported," without "too wide" an "analytic gap" between the conclusion and the underlying data. In other words, to be admissible, the district court must believe that the conclusion is correct. Indeed, this has been petitioners' position from the start of this litigation, in urging that the district court exclude the testimony of Joiner's experts based on their view that the *conclusions* of the experts simply *did not follow* from the studies they cited. See pp. 12-13, *supra*. The district court accepted this construction of Rule 702, holding as follows:

> Assuming that Plaintiffs' experts had not made unfounded assumptions about furans and dioxins, Defendants still persuade the court that Plaintiffs' expert testimony would not be admissible. Defendants do this by attacking the conclusions that Plaintiffs' experts draw from the studies they cite.

App. 58a.

The legitimacy of a construction of Rule 702 permitting such analysis was exhaustively explored by the parties and *amici*, and was rejected by this Court, in *Daubert*. There, the central contention of respondent with respect to the proper disposition of the case was that an overwhelming consensus existed among experts who had studied Bendectin that the drug was safe and could never cause birth defects and that, because the plaintiffs' experts had reached a contrary *conclusion*, their testimony must be inadmissible.[63] As to the distinction between methodology and

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[62] SG Br. 26 (quoting App. 67a (quoting *Turpin v. Merrell Dow Pharmaceuticals, Inc*, 959 F.2d 1349, 1360 (6th Cir.), *cert. denied*, 506 U.S. 826 (1992)); *see also* Pet. Br. 4. Significantly, the Solicitor General does not argue that there *was* an analytical gap in this case, only that the district court's belief that such a gap existed is entitled to deference. *See* SG Br. 30 (entertaining assumption that "reasonable minds might differ on that issue").

[63] *See, e.g.*, Respondent's Brief in Opposition, *Daubert*, No. 92-102, at 1-4 (asserting "overwhelming" and "universally recognized" nature of evidence

conclusion that had been proposed by plaintiffs, respondent in *Daubert* argued that it was "hard to see how to derive [plaintiffs'] distinction from Rule 702."[64]

A number of the *amici* in *Daubert* responded that the distinction between methodology and conclusion is inherent in the concept of "scientific knowledge" and thus necessary for analysis under Rule 702. In particular, leading scientists and scientific organizations explained the nature of scientific inquiry and "scientific knowledge," and urged this Court to construe Rule 702 as focusing on a scientist's methodology, not on his or her conclusions. For example, a brief filed by historians of science including Prof. Stephen Jay Gould noted that "[i]nstead of directly evaluating the methodology of the research on which plaintiffs' experts relied, the Ninth Circuit began with those experts' conclusions and worked backwards."[65] Two of the nation's leading scientific organizations likewise explained, in a passage ultimately quoted by this Court, that: "Science is not an encyclopedic body of knowledge about the universe. Instead, it represents a *process* for proposing and refining

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favoring respondent with respect to the conclusion that Bendectin does not cause limb defects); Brief for Respondent at 5, 11 (referring to the "massive body of uniform scientific research," and "overwhelming body of data" contradicting conclusion of plaintiffs' experts).

[64] Brief for Respondent at 16 n.9. Beyond its assertion that no such distinction could be made under Rule 702, respondent in *Daubert* attempted to muddy the methodology/conclusion distinction through what might be termed a "litigation-by-thesaurus" strategy, by inventing ambiguous phrases to describe the Rule 702 test which lumped together the concepts of methodology and conclusion, in an effort to obscure the distinction between the two. *See, e.g.*, Brief for Respondent, *Daubert*, No. 92-102, at 9 (suggesting "adequate foundation" requirement); *id.* at 10 ("reliable foundation" test); *id.* at 12 ("conclusions that are validated" test); *id.* at 17 ("natural 'accepted-standards-for-validation' meaning" for Rule 702); *id.* at 21 ("'foundation' requirement"); id. at 22 (judge should "screen evidence based on its substance"); *id.* ("foundational inquiry" test); *id.* at 24 ("foundation filter"); *id.* at 26 ("adequate foundation under accepted standards for validation" test); *id.* at 27 ("'accepted standards' foundational requirement"); *id.* at 27 n.18 ("foundational rule"); *id.* at 33 ("proper materials"/"used in reasonable fashion" test).

[65] Gould Br., *supra* note 58, at 5 (citing Opposition to Cert. at 3).

theoretical explanations about the world that are subject to further testing and refinement."[66]

Similarly, a brief submitted by a leading authority on federal evidence, as part of a scholarly foundation's long-term project on scientific evidence, argued that under Rule 702 "courts should focus on determining whether the expert engaged in recognized forms of scientific practice in reaching his or her conclusion," that is, "whether the scientific claim . . . is the product of a recognized form of scientific inquiry," an inquiry that "does not require that the judge understand or undertake an extensive examination of the hypotheses being put forth" or mean "that a federal judge in ruling on admissibility should evaluate the *content* of the scientific evidence."[67]

In its *Daubert* decision, this Court accepted the view of these and other authorities and rejected the argument of the respondent that there was no basis for distinguishing under Rule 702 between the *methodology* relied on by an expert and his or her *conclusions*. In particular, this Court agreed that science is defined by its process, not its product: Science is not "'an encyclopedic body of knowledge about the universe,'" but rather "'a *process* for proposing and refining theoretical explanations about the world,'" and that "[t]he adjective 'scientific' implies a grounding in the methods and procedures of science." 509 U.S. at 590. Therefore, the Court concluded that "to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method," *id.*; that Rule 702 concerns "the scientific validity of [proposed testimony's] underlying principles," *id.* at 595 n.12; that "[i]n a

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[66] Brief for the American Association for the Advancement of Science and the National Academy of Sciences as *Amici Curiae* in Support of Respondent, at 7-8 (emphasis in original) (quoted in *Daubert*, 509 U.S. at 590).

[67] Brief of the Carnegie Commission on Science, Technology, and Government as *Amici Curiae* in Support of Neither Party (co-authored by Prof. Margaret A. Berger), *Daubert*, No. 92-102, at 5, 7-8, 10 (emphasis in original). *See also Daubert*, 509 U.S. at 600-01 (Rehnquist, C.J., joined by Stevens, J., concurring in part and dissenting in part) (expressing concern with any construction of Rule 702 that "imposes on [federal judges] either the obligation or the authority to become amateur scientists").

case involving scientific evidence, *evidentiary reliability* will be based upon *scientific validity*," *id.* at 591 n.9; and that "[p]ertinent evidence based on scientifically valid principles will satisfy" Rule 702. *Id.* at 597.

In sum, as this Court construed Rule 702 in *Daubert*, as long as an expert's *methodology* is valid, his or her *conclusion* is admissible, because it is the product of a scientific process. Under Rule 702, this Court emphasized:

> The focus, of course, must be solely on principles and methodology, not on the conclusions they generate.

509 U.S. at 595.

Petitioners and their *amici* are forced to variously ignore, paraphrase or misquote this passage in the process of arguing that Rule 702 should be construed so that a federal court may only admit an expert's testimony if it appears to the court that the expert's conclusion is *correct*.[68] These verbal somersaults are no more impressive than the similar linguistic efforts made by the respondent in *Daubert*. See note 64, *supra*. The *Daubert* Court recognized that its ruling might result in the admission of *conclusions* that were decidedly against the mainstream — although that is certainly not *this* case[69] — but regarded

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[68] Nowhere in their argument that the court of appeals misconstrued Rule 702 do petitioners even mention this critical passage in the *Daubert* decision. *See* Pet. Br. 46-50. Most of petitioners' *amici* simply ignore it as well; the *amici* who do paraphrase or quote the passage do so in a misleading (even ridiculous) manner. *See, e.g.*, Brief of Chemical Manufacturers Association as *Amicus Curiae* in Support of Petitioners, at 15 (describing *Daubert* as holding that "under Rule 702, a court must focus on the reasoning process and methodology through which they were developed and validated, *not just the conclusions* themselves") (emphasis added); Brief of the Dow Chemical Company as *Amicus Curiae* in Support of Petitioners, at 15 (arguing that under Rule 702, "the essence of what *Daubert* is all about" is whether "the purported bases for an expert's opinion actually support *that opinion*") (emphasis added).

[69] The conclusions of Joiner's experts in this case that PCBs likely promoted the development of Joiner's lung cancer are hardly "controversial," given the conclusion of the federal government and the World Health Organization that PCBs "probably" cause cancer in humans, including lung cancer, and given petitioner Monsanto's own experience. See note 3 and page 4, *supra*.

"apprehension" over this prospect as reflecting undue pessimism

> about the capabilities of the jury, and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.

509 U.S. at 595-96.

In its decision below, the court of appeals faithfully complied with this resolution of the dividing line between the admissibility and the weight of expert scientific testimony, and this Court's admonition that the focus of analysis under Rule 702 must be solely on an expert's methodology, not the expert's conclusion. App. 6a-8a, 13a, 16a-17a. That message has been heeded not just by the court below, but the federal appellate courts generally. *See, e.g.*, *Ambrosini v. Labarraque*, 101 F.3d 129, 133-34, 140 (D.C. Cir. 1996), *cert. dismissed*, 117 S. Ct. 1572 (1997); *In re Joint E. & S. Dist. Asbestos Litigation*, 52 F.3d 1124, 1132-33 (2d Cir. 1995); *Claar v. Burlington N. R.R.*, 29 F.3d 499, 501-03 (9th Cir. 1994); *United States v. Chischilly*, 30 F.3d 1144, 1153-54 (9th Cir. 1994), *cert. denied*, 115 S. Ct. 946 (1995); *United States v. Martinez*, 3 F.3d 1191, 1198 (8th Cir. 1993), *cert. denied*, 510 U.S. 1062 (1994). Beyond the threshold fact that petitioners chose not to present a Rule 702 question in their petition for certiorari, there is nothing in this case or in the briefing on petitioners' side that would call for reconsideration of the arguments that this Court rejected four years ago in *Daubert*.

CONCLUSION

For all the reasons stated, the judgment of the court of appeals should be affirmed.

Respectfully submitted.

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DEPOSITION OF DANIEL T. TEITELBAUM, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

Deposition of DANIEL T. TEITELBAUM, taken on behalf of Defendant General Electric Company, pursuant to Notice of Taking Deposition in the above-entitled action, on Tuesday, October 12, 1993, at 10 a.m., at 3306 Independent Square, Jacksonville, Florida, before Shelli Kozachenko, CSR, RPR, and a Notary Public in and for the State of Florida at Large.

* * * *

[4]

DANIEL T. TEITELBAUM,

having been produced and first duly sworn as a witness, testified as follows:

Q Would you state your full name, please?

A Yes. It's Daniel T. Teitelbaum, T-e-i-t-e-l-b-a-u-m.

Q Dr. Teitelbaum, I see that you have brought with you today a number of items. Would you identify those for the court reporter, please?

A Yes, I will. This is my correspondence file which has correspondence between Mr. Warshauer, other members of his firm, and my office. This blue folder is [5] series of summaries of Mr. Joiner's deposition, Dr. Schecter's deposition, and a case summary prepared in my office of Mr. Joiner's medical records.

Let's make it orderly if we can. This is my chart of my medical examination and history of Mr. Joiner. The yellow

binders, bright yellow binders, are, one, a bibliography and the original papers dealing with lung cancer in animals and humans and PCBs with just a bibliography separate, so in case you don't want to mark the whole thing, you've got the separate bibliography; two copies of the Hazardous Substances Data bank on PCBs dated October 1993, the most recent review being the 7th of August of 1993 under peer review committee; Dr. Schecter's deposition — I'm just going to put that on the floor; I suspect you don't have any particular desire to do anything with that — and Mr. Joiner's deposition, which is in the brown.

In the blue are the medical records of Mr. Joiner which were supplied to me by Mr. Warshauer's office. Do you want to — are you going to want to attach those?

MR. FREEMAN: May I see them?

THE WITNESS: (Tenders the document.)

And then three black binders which constitute the discovery information obtained by Mr. Warshauer's **[6]** firm which was sent to me in connection with the case; a single page which represents one of what I understand are many analyses of PCB-containing mineral oils in the various transformers, but this is just a single one, and it's reproduced also in the blue folder; and then the original complaint which was filed in the case.

Q And I notice you have some books there as well.

A Yes.

Q What is the red book?

A The red book is the second edition of the International Program on Chemical Safety, the World Health Organization Environmental Health Criterion on PCBs which was just released. It's a 1993 publication, the update of a previous — which I think was 1979, if I remember correctly. And this is the June 1989 ATSDR toxicological profile for PCBs.

MR. COCHRAN: All right. If we could, I want to mark all these as exhibits.

* * * *

[11]

Q Now, I think you indicated that you had in a yellow folder a bibliography?

A Yes. I have a bibliography entitled "Lung Cancer and PCBs."

Q All right. What you have here is first you have a bibliography, then you have a bibliography with abstracts —

A Right.

Q — and then you actually have —

A The articles.

Q — the articles themselves.

A Correct.

MR. COCHRAN: Okay. Why don't we mark these as 12A, B, and C.

(The instruments were marked for **[12]** identification as Defendant's Exhibits 12A, 12B, and 12C.)

Q Have the bibliography, the bibliography with abstracts, and the actual articles themselves now been identified as Exhibits 12A, B, and C?

A Yes.

Q And who compiled the bibliography?

A I compiled the bibliography. My librarian actually put it in the technically correct form.

* * * *

[19]

Q Dr. Teitelbaum, do you have in front of you your handwritten notes from when you met with Mr. Joiner?

A Yes, I have my notes and my summaries of the deposition, and I will shortly answer your question.

Q All right. When did you make these handwritten notes, by the way? On what date?

A As I was sitting and discussing them with him, and I saw him on 7/14/93.

Q Where did you see him?

A In Atlanta.

Q Where in Atlanta?

A In a physician's office, and I'm sorry, I don't remember the doctor's name. **[20]**

Q How long did you meet with Mr. Joiner?
A About two hours, perhaps two and a half.

* * * *

Q What was the purpose for you making these handwritten notes when you interviewed him?

A It's a history. When I take a history from a patient, I begin at the beginning of the story and try to write as complete a story as the patient chooses to tell me, and then I ask him specific questions. And eventually I hope I have a complete picture of what the patient did, what's wrong with the patient, what the patient's present and past complaints were, something about family history, and so on. It's a fairly traditional medical exercise.

* * * *

[21] Q When you met with Mr. Joiner on July the 14th of 1993, did you conduct a physical examination of him?

A Yes.

Q What did you do?

A There's a notation of physical examination. I did as complete an examination as one could do not [22] working in one's own office, but actually there was pretty much everything that I needed, and so I did a typical examination just as — about the same as what I would have done had I had him in my own office, took his vital signs and went through and looked at him. I did not do any laboratory work, but I did enough of an examination to know what his condition was at the time that I saw him.

Q All right. You say you didn't do any laboratory work. Did you order any blood tests?

A No.

Q Any other diagnostic tests?

A No. He's had a very large amount of laboratory work, most of it quite recently. There was no reason to do that.

* * * *

Q All right. Now, let's see. What else do we have there?
A Just these two — the ATSDR document and the WHO

criterion document.

[23]

Q All right. If you would, identify on the record what they are.

A Yes. The first is the Environmental Health Criterion Number 140 entitled Polychlorinated Biphenyls and Terphenyls, Second Edition, World Health Organization, Geneva, 1993. It carries ISBN Number 94-4-157-140-3, and you can get it from WHO for 70 Swiss francs. I think they have a publications office in Albany, New York.

And then the second is the Toxicological Profile for Selected PCBs, published by the Agency for Toxic Substances and Disease Registry in June of 1989, and you can get this from the U.S. Department of Commerce, National Technical Information Service, Springfield, Virginia 22161. Carries the document number PB89225403.

Q Are there any other documents that you have reviewed which we have not identified this morning for purposes of this case?

A No, I read every month. We do a current awareness survey on PCBs, and so I have volumes of articles on PCBs that I've collected and read over the years, but I don't think they're particularly relevant [24] to this morning's discussion.

* * * *

[26]

Q Now, I noticed at the beginning of Dr. Schecter's deposition, you had sent a medical evaluation to his office on the evening or afternoon before his testimony.

A I didn't send anything to him. Mr. Warshauer may have sent a copy of the chart to him. I have never discussed this case with Dr. Schecter, never had any correspondence with him, and never sent him anything.

* * * *

[28]

Q All right. If you would, Dr. Teitelbaum, would you simply tell us what opinions you have reached in this case?

A Yes. I would say I have three opinions. The first opinion is that to the best of anyone' diagnostic capacity, Mr. Joiner had lung cancer and has been treated and is currently in remission from that lung cancer.

Secondly, it's clear that for a period of many years, Mr. Joiner worked as an industrial electrician and had exposure to various materials commonly used in that trade, including mineral oils contaminated with PCBs.

And, there, that his lung cancer was caused by or contributed to in a significant degree by the materials with which he worked.

* * * *

[31]

Q Do you know from any source what concentrations of PCBs were contained in any of the transformers on which he worked?

A I don't have those documents. I understand there are such documents; I have not seen them. Typically, in my experience, transformers which were listed as non-PCB transformers throughout this last 20 [32] years had concentrations from anywhere above 50 parts per million to something under 1 percent, maybe 5,000 to 8,000 parts per million at the maximum.

Q And is that something you're assuming for purposes of your opinion?

A Well, it's fairly typical of the era. I think it's reasonable to assume that that's so, yes.

Q All right. Do you know how long Mr. Joiner was exposed to mineral oil contaminated with PCBs, how many years?

A Well, he began work in 1973, and he says he thinks he stopped sometime around 1987.

Q So you would be assuming a 14-year exposure?

A That's what he believes he was exposed — that's the period that he says. He says he does not know what the situation was after that.

Q In reaching your opinion, though, what length of time are you assuming?

A Well, that's the assumption that I have, because I have no history of his having worked with these materials before 1973. His medical history prior to that indicates that he worked — did a little farming, some farm chores early, and worked as a

delivery boy and stocker — let me get the exact — baled hay and picked watermelon while he was in high [33] school up to 1972, and then in 1973 he began to work for the public utility.

Q Now, during the years that Mr. Joiner may have been exposed to mineral oil contaminated with PCBs, how often, if you know, was he exposed?

A I don't have, and have not seen that anyone has collected, the transformer records for who worked on them. I don't know how this utility works as far as its record maintenance is concerned, but other utilities that I've looked at keep a log for every transformer, and actually one could set up a record of how many he worked on, but how many hours it took him to do each job, it would be difficult to say. But from his descriptions to me, it was a very frequent activity.

(Mr. Freeman leaves room.)

Q On the order of daily?

A I would say several times a week, not necessarily daily. It's more likely that there were periods that were quite intensive and went on for a number of days when he was working on a large transformer and baking it out, something of that sort, than that it was every day. So I think it was episodic but not every day.

Q Have you seen any documents that would reflect the presence of dibenzofurans, dibenzodioxins, [34] or chlorinated benzene in any of the mineral oil on which Mr. Joiner worked on or around?

A I don't have any documents which would answer that question. There are, so far as I can tell, no quantitative analyses that have been supplied to me that answer how much and when.

(Mr. Freeman enters room.)

Q Or if any; is that correct?

A I don't have any documents at all. I think that one simply has to look at the likely chemistry of the situation and what's known about PCBs manufactured in this period and assume that there was some furan present, that there may have been some dioxin present, depending on the particular fire and circumstance. There probably was some chlorinated benzene since that's almost always a contaminant.

Q But that's speculation on your part in this case, is it not?

A No, it's not speculation. It's a reasonable assumption based upon what we know about the era.

* * * *

[44]

Q I want to make sure I've covered your second opinion. Have you, as far as you know, given us all of the facts on which you base that second opinion, that Mr. Joiner for many years had exposure to various mineral oils contaminated with PCBs?

Q Well, I haven't talked at all about how he worked and the conditions under which he worked, all of which contributed to that.

Q All right. Tell me what facts you rely upon there.

A Well, for the first, at least, 12 to 13 years of his work he had no protective gear. He worked with [45] and in the oil on a regular basis. He describes frequently having his skin doused with oil. He describes needing a new pair of shoes every six months because of the oil destroying his shoes. He describes being inside the larger transformers on many occasions and being covered with oil. He describes inhaling the smoke on a number of occasions from baking out transformers.

He describes his desk as being in the area where the transformers were actually being serviced, so that — and his tools being constantly covered with oil. Again, this is very typical. Every electrician that I've ever talked to from this era told me that they used to use the oil from the transformers to oil their tools to prevent rust and to keep them in good shape. So he has multiple exposures by dermal and respiratory route.

* * * *

Q All right. Now, let's turn to the third opinion which was that — and I'm paraphrasing, so if [47] you want to go back — if I misphrase this, feel free to correct me, but as I understood it, your opinion is something like the lung cancer was caused by or contributed to in a significant degree by the materials with which he worked.

A Good notes.

Q All right. Now, tell me the facts on which you relied in reaching that opinion.

A Well, it's my opinion that cancer is a multifactorial disease. As a consequence of this multifactorial pattern of causation, various individuals respond with malignant disease at some time in their lives, and it is unusual for a single cause to be identifiable.

In my analysis of the information available concerning Mr. Joiner, I find three interesting factors. The first interesting factor is that there is at least one case of lung cancer in a first-order relative. There is not much evidence that sporadic cases of lung cancer have a familial pattern. There are recently some interesting studies on families of lung cancers, but they're pretty unusual. But there is at least one case in a smoker in his family. That's the first interesting thing.

The second interesting thing is that we do [48] know that Mr. Joiner smoked for a relatively significant period of his life, but from the point of view of causation of lung cancer, a very — a low-end dose and early, and he stopped 12 years approximately before he got sick. But if the most recent studies on smoking and cancer are correct, our previous assumptions that as time passed the risk would disappear may have been unduly optimistic. So we have some risk of lung cancer because he was a smoker; however, the likelihood of his developing lung cancer at age 37 on a statistical basis is extremely small.

If you compare the lung cancer rates at age 60, which are around 400 per 100,000 person years, with the lung cancer rates in the 30s, which are almost too low to detect, somewhere around 10 to 15 per 100,000 and most of those in the later 30s rather than the early 30s, it's pretty — pretty low risk, but it's there.

The third thing is that we have a period of approximately 15 years of exposure to a material which, in and of itself, is an animal carcinogen, likely contaminated with additional materials which are animal carcinogens, carried in a vehicle which is a known carcinogen, and other work which he did which had some potential carcinogen exposure. It's not quite so clear, but he talks about using mineral oil as a — using [49] mineral spirits as a cleaning solvent.

So I see his occupational exposure to the materials containing — to mineral oil containing PCBs as a significant portion of his history. I am a firm believer in the concept that if there is more carcinogen exposure, there is more risk of cancer and more cancer

in fact, and I believe that in that fashion, at least these three issues, some perhaps genetic predisposition, not well characterized, about which we know very little; smoking, about which we know more; and an occupational carcinogenic exposure to a material known to be an animal carcinogen and quite strongly suspected by most people being a human carcinogen as well, I think that those elements together are a significant portion of the causation of this disease.

Q Now, which of these substances is the known animal carcinogen?

A Well, I think that there's very little question that PCB is. There's sufficient information on PCBs. I brought the IPCS World Health Organization criterion because it's just hot off the press, and the summary which appears on page — let me find it — 478 indicates that as of 1987, IARC had concluded that the evidence for carcinogenicity in laboratory animals is sufficient. This is the latest piece of information, **[50]** and there is no reason to doubt that, and they also concluded that PCBs are probably carcinogenic for humans.

Q Is it your opinion that Mr. Joiner's lung cancer was initiated by his cigarette smoking?

A I don't have an opinion about that. That would be purely speculative. It could have been. It could have been initiated by something entirely other than that. I think what's clear is that when you stop smoking, the promotional effect goes away, at least the nongenotoxic promotional effect.

Q The promotional effect of what?

A Of the cigarette smoking.

Q Is cigarette smoking a complete carcinogen?

A Hard to answer the question. I think there are components in cigarette smoke that have the potential for being complete carcinogens. For example, ethylene oxide is present. I think ethylene oxide can be both a promoter and an initiator. On the other hand, there are — and there are anthracenes and various polynuclear aromatics, all of which appear to have the capacity to be complete carcinogens.

On the other hand, there are a lot of materials which are only initiators, like urethane which is in cigarette smoke, or the tars which are probably **[51]** purely promoters. If you go back to the earliest research in cancer, the Rouses' work on chicken papilloma,

the promoter used in those tar, coal tar in that case but not terribly different from cigarette tar.

* * * *

[61]

Q All right. In addition to mineral spirits, cigarette smoke, and PCBs, were there any other chemicals in Mr. Joiner's workplace that contribute to your opinion?

A In the occupational/environmental history which I took from him, he listed oil and paints as the only other two materials, the oil being something apparently other than the PCB oil, and the paints being apparently an occasional exposure. And I would think that the paints, if they're a problem, are a problem because they contain mineral spirits in some instances. That's all he indicated he worked with, so that's all I would point to. I don't have anything else.

* * * *

[65]

Q All right. You've identified oil, you've identified paint, you've identified mineral spirits, you've identified PCBs. Is there any other chemical that was present in Mr. Joiner's workplace that you believe contributed to his lung cancer?

A Not according to anything he told me. I don't know of any other chemicals that were present, period. That's all we have.

* * * *

[70]

A Can you say to a reasonable degree of medical probability whether Mr. Joiner's body burden of PCBs was higher than background nonoccupational levels before his diagnosis in August of '91?

A I have no opinion about that. It would be pure speculation.

Q Why would it be pure speculation?

A Because you don't have a measurement from before; you don't have any way of comparing it to the general population; you don't have anything that you could base that on. It would be absolutely a guess.

[73]

A In my opinion, exposure is all that can be calculated in this, and that would be a very rough calculation which an industrial hygienist might do, taking a very careful history of, let's say, a series of incidents and then setting up a model for how much of this PCB would have been on the skin of the individual, how much PCB and mineral oil would have been in the air, depending on the temperature and so on, and then you come up with a total exposure assessment. That would be different from the dose.

Q You haven't done any sort of modeling in this case, have you?

A Well, I don't have enough data to do that. Obviously I'd have to start out by knowing what's in the material, and that hasn't been provided to me if it exists.

Q So you don't have any quantitative data to assess either exposure or dose here.

A That's correct. I would not have any way to do it. I don't have any reliable measure of PCBs in his body before he became ill. I don't have any reliable information concerning the contamination. I only know that in the era we are talking about, the typical [74] materials were contaminated, as I've previously discussed, and he worked with it over a long period of time, and material is absorbed through the skin. That's as far as we can go.

And that's typical of what we know in retrospect in industrial hygiene or occupational medicine studies. The person who is ill can rarely give you anything more than that.

Now, when we come back to this table 20 years from now, both of us grayer and older, perhaps we'll be able to look at numbers which have been collected since 1985 which will tell us enough so that we can, in fact, model the exposure.

* * * *

[81]

A . . . The concept of cancer or carcinogenesis as a biological problem is discussed in at least two — I think two good books. One is Hathway's book on chemical carcinogenesis, and the other is Berenblum's book, that's entitled Carcinogens as a Biological Problem. There are lots and lots of papers, Farber's papers and Smuckler's papers and many others, in which the attempt to understand the strategy of carcinogenesis is laid out.

I think that it is a multifactorial disease.

* * * *

[83]

A . . . A promoter by definition is never a complete carcinogen. It may, in fact — a complete carcinogen may have both initiating and promoting qualities, but you can expose someone to a promoter forever; if they don't have an initiator, they will never get cancer. So it's necessary, but not sufficient.

* * * *

[84]

Q Well, if a chemical as a general matter is characterized as a promoter of cancer in humans, do you [85] classify it as a human carcinogen?

A It might be, but it is a chemical which participates in the generation of cancer. See, this is really a — it's a failure of the current terminology because our regulatory system and the scientific knowledge are not necessarily concordant. You surely don't want to go around exposing people to promoters.

Q Is that because they have a — as a general matter they would have a carcinogenic potential?

A No, it's because they would cause more cancer, but not because in and of themselves they're carcinogenic. And I think we're playing with words here. I think it's like saying if you need a detonator and dynamite together to get an explosion, is the detonator considered an explosive? And it may be for the Alcohol, Tobacco, and Firearms Division, and you maybe would get charged with possession of explosives if all you had was the detonator in your hand, but that isn't going to blow up.

Q Well, let me ask you this: When we distinguish between the term carcinogenic and the process of carcinogenesis, you would include a promoter within that process.

A It's part of the process. I think that that is clear. I think that if you read Berenblum's book [86] which presents — unfortunately, since he's passed away no one's gone back and redone it; it's a mid 1970s analysis. He takes every theory of carcinogenesis which had been proposed as of that time and critiques it logically. It's a brilliant piece of work on cancer, and he lays out all those issues.

Or you read I. B. Weinstein's papers on co-carcinogenesis. And I think that our concept of complete carcinogens is very limiting, probably only relates to ionizing radiation in and of itself and some alkylating agents like ethylene oxide and one or two others where it's clear that it both initiates and promotes.

For most substances you have a mix, and you have to have the substances together to produce cancer. The way we define it in a regulatory sense, or the way IARC defines it, is if you have more of this, then you get more cancers in animals and people, and it really doesn't matter what the fundamental mechanism is, is it an initiator, a promoter, a complete carcinogen, a co-carcinogen, a modifier, a penetration enhancer, or any of a lot of things.

Q All right. Is consistency a principle of toxicology?

A Consistency is a principle in science. In **[87]** theory you should be able to do an experiment a certain number of times and get an outcome more often than due to chance.

Q All right. Let me ask you this: Based on the animal studies that you're aware of, has there been a consistent causation by means of promoting of lung cancer in two different animal species?

A That sounds like a regulatory definition, and I just don't think I'm going to be able to answer that. I think that's got words in it I don't understand.

Q Which words don't you understand?

A Well, I know what consistent means scientifically, but I don't know what consistent means in that sentence. Are we talking that if you did a hundred studies, it would be more often positive than you would expect due to chance? Is that what your definition is?

Q Other than the studies by Lucy Anderson, do you know of any other animal study where lung cancer was promoted in a species other than mice?

A I don't think anybody's studied any other study. I think that now that the 1993 Anderson publication came out, I suspect you're going to see some more studies on that because now there seems to be a clean model that can be looked at. **[88]**

Q Is biologic plausibility a fundamental principle of toxicology?

A Yes.

Q All right.

A Well, no, wait. It's not a fundamental principle of toxicology, it's a fundamental principle of epidemiology, and it comes from Bradford Hill's criteria, and it is a fundamental principle which attempts to assess inference of causality based on scientific study.

Q Is it sufficient to establish biological plausibility to find carcinogenesis in only one animal species?

A It's a pretty good start. I mean, I think it is —

Q Is it sufficient?

A I think it's sufficient when you have all of the other information you have about PCBs as carcinogens. It's perhaps not sufficient to establish that a particular kind of cancer would occur in all animal species, but it certainly is much more consistent with the total body [sic] than if she had not found it.

If you came to me and you said, "Dr. Anderson had done this study and it's negative. Is that consistent?" I would say, "No, that's not consistent. **[89]** That's perhaps revolutionary." In fact, I would think that if you studied any kind of cancer well, you would find that it's probably — that PCBs are probably capable of promoting that cancer in a particular study design.

MR. COCHRAN: All right. Would you read that answer back to me, please, ma'am?

(The preceding answer was read by the reporter.)

THE WITNESS: Body of knowledge, I think, is what I said.

THE REPORTER: Oh, I'm sorry.

BY MR. COCHRAN:

Q Now, turning to your bibliography, I think we identified as Exhibit — is it 12A?

A Yes, right.

Q All right. What, if any, epidemiological studies have you reviewed in reaching your opinion?

A Well, I think I've reviewed all of those that are around on PCBs. I think that the study which in the long run will give us the most information is probably Bertazzi's group. I just saw Professor Bertazzi in Nice and I asked him if he has anything new coming out, and he says yes, he has something new coming out, but he wouldn't tell me what it was, so I don't know what it **[90]** is. Apparently, they've done some further study of this group of capacitor workers.

He could have another five years of observation, which would be a lot of person years. I think that's the best study. You've got Kuratsane's studies from Japan. You've got a few cases of lung cancer there. They're not very convincing, as the Japanese lifestyle is different. There's — it's, again, suggestive but not convincing.

I think that the recent review by IARC of all of the studies, including Gustavsson, who was also at the meeting, and Hogstedt, who was also there, and — all of whom talked about this, I think everybody is willing now to take the position that PCBs are human carcinogens, but I don't think that they would — any of them would be willing to say that they have evidence, convincing evidence, that PCBs cause any single kind of cancer.

I think they would say that they are human carcinogens and that the evidence now is that they can promote a whole series of cancers: hematologic, kidney cancer, certainly lung cancer is on the list. They've been observed and they appear to be out — by Bertazzi's work, well out of proportion to what would be expected.

Q Okay. You said you have reviewed all of the [91] epidemiologic studies. Are there others that you have reviewed that are not on that list?

A These primarily were the ones that dealt with — that mentioned lung cancer and so on. Yes, there's a whole series of them listed in that WHO document, and I've — whenever one comes out, I collect it and I read it.

Q Do all of the epidemiological studies show the same thing; that is, are they consistent?

A No, but — all do not, but there is certainly general agreement that for groups which have been studied long enough and for which the exposure is well enough characterized, there is an increased risk of cancer in humans. But you have a vary varied group. You have groups where you have mostly women exposed; you have groups where you have mostly men.

Most of the studies come from capacitor workers, not from people who did this kind of — the work that Mr. Joiner has done. I don't know of a study in industrial electricians. Be interesting to do, but I don't know of such a study. And probably it would be one you could do because a lot of these people belong to the unions and would be fairly easy to identify.

Q Did the Bertazzi study have a very short follow-up period?

[92]

A Yes, that's why I said he — he published it in '87, and I think he wrote it about — sometime in '86. We could theoretically have another five or seven years of follow-up, but he says he has something in the works, but wouldn't tell me anything about it.

Q If an epidemiological[] study has a short follow-up period, does that put a limitation on the interpretation of the results?

A Can put a lot of limitations. If you're dealing with something which is very highly penetrant, a disease which occurs quickly and very often, like if you study leukemia in radiation victims, and you've got five years of follow-up, it's clear in five years that you're going to have an increase in leukemia in people exposed to radiation.

On the other hand, where you're dealing with something which is a relatively weak carcinogen and a relatively rare disease — I mean, if you wanted to study PCBs in electricians at age 35, I haven't done the calculations, but you'd need millions, I think, millions of exposed people to get a statistically significant finding, or millions of person years anyway.

Q What was the size of the cohort that Dr. Bertazzi studied?

A I think 1500 approximately. .... [93]

Q So would that, again, having a small cohort, be a limitation on his results?

A Got to wait longer.

A Well, you need a number of person years of exposure and a number of person years of follow-up. You can get the number of person years of follow-up by having a big group for a short time or a small group for a long period of time. A thousand person years of follow-up standardized over, they may give you an answer comparing studies, but —

Q Then would the study be inconclusive due to low statistical power?

A That's one of the accusations that have been made, and he himself says that they — you know, that the lung cancer occurrence was tending or trending towards statistically significant, but was not statistically significant.

That doesn't really mean anything, as you well know, because statistical significance is not the only criterion for interpreting

information. It suggests [94] that there may be an error in the study, but if it's biologically plausible and it's consistent with other studies, even though it doesn't reach statistical significance, you'd best be very, very cautious in saying the effect isn't there.

* * * *

[95]

Q All right. Let me ask you: Based upon the epidemiologic studies that you've seen, is there a finding of a significantly increased incidence of cancers of a general type in an exposed population when compared to an unexposed population in a carefully documented epidemiologic study?

A I think that's a subject for a doctoral paper, [96] and I'm going to say it's too vague for me to answer. You're going to have to tell me what you mean. Are we talking about all cancers? Are we talking about general populations? I think that the question you're asking me now has been answered by the expert committee that IARC had together, and their conclusion was there's enough evidence to say that it's probably a human carcinogen, there is not enough evidence to say that is proved, and I think I would have no problem accepting that.

Q And when you say that it's a human carcinogen, you're just talking about generally without respect to any particular —

A That it's capable of causing cancer in humans, without saying which cancers it's capable of causing. I do not believe that there's any good evidence that PCBs in any specie have a signal lesion. I mean, we have a whole series of cancers which have been observed as increased: kidney cancer, lung cancer, hematopoietic cancers. I've even seen one study on prostate cancer. Lots of opportunities.

Q Are there criteria which you as a toxicologist should meet to reach a conclusion to a reasonable degree of medical probability?

A About what?

Q Causation. [97]

A There's a nice discussion — there's a new little paperback epidemiology text by Greenburg and a group of colleagues in which he talks about the difference between probable as used by clinicians and probable as used by epidemiologists, and he points out that probable as used by clinicians is what most of the

world runs on. That is to say you look at all the information and you come to a conclusion that all the evidence together gives you the reasonable likelihood that your conclusion clinically is correct.

I think that as a toxicologist when I look at a study, I am going to require that that study meet the general criteria for methodology and statistical analysis, but that when all of that data is collected and you ask me as a patient, "Doctor, have I got a risk of getting cancer from this?" That those studies don't answer the question, that I have to put them all together in my mind and look at them in relation to everything I know about the substance and everything I know about the exposure and come to a conclusion.

I think when I say, "To a reasonable medical probability as a medical toxicologist, this substance was a contributing cause," this substance being the contaminated oil was a contributing cause to his cancer, that that is a valid conclusion based on the totality of — [98] the evidence presented to me. And I think that that is an appropriate thing for a toxicologist to do, and it has been the basis of diagnosis for several hundred years, anyway.

MR. COCHRAN: Let's take just a short break, if we could, Michael.

MR. WARSHAUER: Okay.

(Short break.)

BY MR. COCHRAN:

Q Did you recommend that Mr. Joiner undergo any other diagnostic tests, x-rays, CAT scans, anything else like that?

A Oh, heavens, not at this time. I certainly wouldn't expose him to any more radiation. He's had enough radiation at this point. If he needs therapeutic radiation, you don't want to use up his potential exposure on unnecessary tests.

* * * *

[106]

Q So how often do you testify?

A By deposition?

Q Or court appearance or at a hearing.

A In court, not more than three or four times a year, maybe five times a year maximum, some years not at all. I think in '90 — was it '91 or '90, there wasn't a single court appearance. By deposition, perhaps three or four times a month.

* * * *

[110]

Q Now, to be specific to this case, is there any study that you know of anywhere in humans that indicate that small-cell, being specific to this diagnosis, lung cancer was caused by PCBs?

A No. It's an impossible research question to investigate, I think, in the first place, and in the second place, there is no such study.

Q I see.

A So I think it's — in other words, I think that you couldn't do the study, and I don't think one exists at the present time. [111]

Q I see. The same question with respect to PCBs as contributing to small-cell lung cancer in humans.

A That, I think could be done, but has not been done.

* * * *

Q Now, can you point to any study in animals where the person conducting the study has suggested that the animal developed small-cell lung cancer?

A I don't think there's an analogy in animals that would be relevant, so I can't point to such a study. [112]

Q Okay, sir.

A We've talked about the Anderson studies. I've given you the bibliography which I consider to be relevant. I do not believe that there is an animal cell type which is sufficiently similar to say that you could conclude A was the same as B. It's rather different from, say, osteogenic sarcomas where you have a better comparison, but perhaps more like the lymphoma/leukemia problem where animals seem to develop analogous lymphomas but not analogous leukemias.

Q Dr. Teitelbaum, I'm going to ask you a few questions, and I won't move if Michael will back up a little bit and you can hear me.

As I understand it, you work for a corporation?

A I have what's called a professional corporation. You can call it that.

Q What is the name of your corporation?

A Daniel T. Teitelbaum, M.D., Inc.

Q And you own 100 percent of the stock in the corporation?

A Yes, that's correct.

* * * *

[114]

Q — what do the other 14 employees do?

A Well, I have four people who work in my clinical are and do typical nursing, and I have an x-ray tech and a laboratory person and so on. I have two full-time library sciences people and at least one assistant in addition. I have —

Q What do they do, library science?

A Well, you see, you've got a bibliography here which is carefully put together. We have more than 40,000 articles catalogued, all of which have been read and assembled, and they're all accessible through computer databases and so on.

Q They keep up with the literature and —

A I keep up with the literature, and they do what I need technically in order to have the literature in front of me, to have it assembled and so on. We have — we're part of the National Library of medicine system, and we actually have the beset toxicology collection in the area. People borrow from us rather than the other way around. We get 46 journals in toxicology.

* * * *

[116]

Q Now, you said you took the examination of — [117] the medical examination and history of Mr. Joiner in Atlanta?

A Right.

Q And who attended that history with you?

A Just his wife and us.

Q Okay. The three of you in the room the entire time, or did she leave the room?

A No, she stayed the whole time.

Q And no one from the attorney's office?

A Mr. Terry — I'm sorry, I don't remember his name — came with us, but no —

Q Did not stay in for the examination?

A No.

* * * *

[118]

Q Now, you referred to this book and I think specifically this book is called The International program on Chemical Safety, Environmental Health Criterion 140, PCBs, Second Edition.

A Right.

Q And you referred, I believe, to page 478.

A Right, the summary page.

Q 477, which is paragraph — all right, 478 which is the first — let me see if I can find this. First paragraph, which says that PCBs were evaluated by IARC in 1977 and 1987. In 1987 the IARC concluded that because the role of impurities in PCBs and the carcinogenicity could not be excluded and because of the lack of knowledge on dose response relationships, the evidence from epidemiological studies is limited. However, the evidence of carcinogenicity in laboratory animals is sufficient, taking the combined evidence from human experimental animal studies, the IARC group concluded that PCBs are probably carcinogenic for humans.

A Right.

Q And you agree with that statement?

A Yes, I do.

EXHIBIT 12-A TO TEITELBAUM DEPOSITION

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DEPOSITION OF ARNOLD J. SCHECTER, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

Deposition of ARNOLD J. SCHECTER, M.D., held at the Bache Building, Binghamton, New York, on the 14th day of July, 1993, commencing at 9:15 AM.

* * * *

[4]
ARNOLD J. SCHECTER, M.D., having been called as a witness, being duly sworn, testified as follows:

* * * *

Q Were you served with a subpoena, a copy of which I've marked, it's the second two pages, as Schecter Exhibit 1?

A Yes, sir.

Q Let's turn to the third page of the exhibit which is attachment A.

A (Witness complies)

Q With respect to the first numbered item, "Any and all published articles evidencing any and all research conducted by or participated in by you concerning PCBs, dioxins, dibenzofurans." All such [5] articles, were those made available to me yesterday in your library?

A You had full access to my office and library yesterday, yes, sir, when you were present in my office.

Q Am I correct that after we conclude today, if we have time, I can go back and take a further look at those materials?

A Of course.

* * * *

[6]

Q Looking at the records I'm going to hand you, were these the medical records that were produced yesterday, is that all of them that you've seen that were produced yesterday?

A No. I believe that in addition to this, there was one other fact that came at the end of the day.

Q What was that?

A That was a medical evaluation from Dr. Teitelbaum.

Q Have you reviewed that?

A No, I have not. [7]

Q Did it form any basis of your opinion?

A No, sir, it did not.

Q Did you read it?

A No, I did not.

* * * *

[16]

Q Have you seen or reviewed any photographs or video-tapes concerning this case? [17]

A Yes, I have.

Q What have you seen?

A I saw a videotape of the work area where Mr. Joiner worked and I believe still works.

Q When did you see this videotape?

A I saw that in the last few months in Mr. Warshauer's office in Atlanta, Georgia.

* * * *

Q Tell me what you do recall about the videotape.

A I recall seeing a work area that was underground, was rather small, no particular separation of toxic chemicals from desk work areas. No worker safety gear or no evidence of separation between the areas where toxic chemicals would be present from transformers and ordinary desk eating, smoking or work areas.

* * * *

[19]

Q Have you ever been to Thomasville, Georgia?

A No, I have not. I would add one comment on medical records. I assume you are speaking of traditional medical records. There are, of course, also adipose tissue chemical levels that were done on this patient.

Q But you don't have those records in your files, do you?

A To the best of my knowledge, I do not.

Q Have you ever been allowed to review those records?

A Yes, I have.

* * * *

[24]

Q In your standard practice, isn't it routine and customary for you to have blood tests run so that you can get a congener — congener specific level determined for dioxins, furans and PCBs?

A No, it is not.

Q To your knowledge, has another blood test for Mr. Joiner to determine dioxin levels actually [25] been done?

A Not that I know of.

Q Do you know why?

A I'd be happy to share with you my evaluations as to the usefulness of doing it, if that's what you are asking me or would like to know about it.

Q The question is: Do you have any knowledge as to why it was not done?

A Well, I suggested — I did not suggest. I informed Mr. Warshauer and his colleagues that we do not know how to interpret blood or adipose tissue dioxin, dibenzofuran or PCB analytic data after cancer and cancer chemotherapy and radiation treatment of cancer. Particularly with weight loss and then weight gain, there is no published research that I'm aware of, and this is a field in which I work full time, concerning how best to interpret or how to interpret meaningfully such data. So, to order a test when you don't know how to interpret it is not usually something I do in my practice of medicine. And it's an expensive test. It's a $2,000 test usually for a day in a dibenzofuran analysis. It's not one to be entered upon trivially [26] and certainly not if you don't think it's going to be useful within the practice of medicine.

It would be an interesting research project which I have proposed, as you may or may not know, that we look into how to interpret these tests in cancer patients.

* * * *

[28]

Q What scientific research or articles in your methodology of analyzing this, what scientific articles or other empirical data are you relying on for this conclusion, for this opinion? Can you name an article for me?

A Well, as I mentioned to you previously in my own published article on dioxin levels in AIDS patients, we found that in a cross-sectional study which has been published, pooled blood from sick AIDS patients had an elevated level of dioxins as compared with HIV infected and that is the virus that causes AIDS infected patients who were not sick or asymptomatic. And also, the levels in the sick AIDS patients were elevated as compared with the general population without the virus. The interpretations included what appeared to us to be quite logical and that was that the treatment may [29] have affected the levels of these chemicals.

Q It may have, you just don't know?

A It may.

Q You don't know?

A Let's follow logically. If your colleague who weighs considerably more than you and has more adipose tissue, probably has 30 percent adipose tissue as compared to your 20 percent, if he were to lose — let's say he had this — a special exposure to dioxins[,] dibenzofurans or PCBs and had an arbitrary value of 100. If he loses half of his adipose tissue, then half of those chemicals in his body would be gone. If he then regained his weight, the new adipose tissue would not necessarily reflect. It would reflect the dilution because he would only have a portion of the chemicals to which he was previously exposed. I think that's straightforward logic and whether that's in a published article or not, I don't know.

* * * *

[32]

Q Where did you meet Mr. and Mrs. Joiner?

A [33] In Mr. Warshauer's office in Atlanta, Georgia.

Q Why did you meet them?

A I wanted to talk to them to get a feel for Mr. Joiner, to be able to have him describe to me what his exposure was in general, what his occupations had been like, what his chemical exposures might have been, what his medical history may have been to get a feel for what kind of person he was, whether he was a person I would find believable or not believable, to evaluate him and his cancer and to try to come to some conclusion as to the causation of his lung cancer.

Q Was there any other reason for you to meet him?

A Not that I can think of at this time.

Q Now, you are an MD, is that correct?

A Yes, sir.

Q Did you physically examine Mr. Joiner?

A I don't remember — I certainly did not do a complete medical exam or complete physical exam. I don't remember whether I did anything specific such as look at skin, I don't recall taking a blood pressure. [34]

Q Did you take what some folks would refer to as your little black bag with you?

A I don't recall doing that. But I could have and I might not have. I just don't remember at this time.

Q Did you take his blood pressure?

A I don't remember.

Q Did you listen to his heart or lungs by means of stethoscope?

A I don't remember.

Q Did you take his temperature?

A No, I did not.

Q Did you order any tests for him?

A No, I did not.

Q Why not?

A Because he had a very thorough workup for his lung cancer and had been under intense medical care for a number of years when I saw him and I didn't want to put him through any more unnecessary hardship and I didn't feel the need for it.

* * * *

[40]

Q Now, what did Mr. Joiner tell you?

A He told me about his work history. He told me about his smoking history and about the diagnosis of his lung cancer. To a certain extent described his treatment and how he felt as far as having strength or not having strength, being tired all the time.

Q All right. He told you about his work history, he told you about his smoking history, he told you about the diagnosis, about the treatment and about how he felt.

A And a little bit about his family history, medical history.

Q And his family medical history. All right. Let's turn to the work history. Tell me everything you recollect he told you about his work history.

A Well, the major point I recall was that he started after high school about 1973 working in the job or for the firm he worked with, the government and the city and progressively moved up in seniority. That he handled electrical transformers and when he first handled them, including maintenance done on them by heating the [41] cores inside with hot lights, he did not have any knowledge that there may be — that there might be toxic chemicals involved. There was no warnings, he was given no instruction and he took no precautions with respect to person protective gear. And the cores of large transformers or smaller transformers were heated in some cases in the office below ground level where he worked. He also worked outside. He took courses to increase his knowledge and to move up progressively and he was still working, much to my surprise for the same company and in the same job.

* * * *

Q What else did he tell you about his work history?

A He told me that in a certain time in the 1980s he learned that PCBs were contaminates, PCBs were sometimes found or believed to be found or actually measured in some of the transformer oil [42] that he was working with and that somewhere in the 1980s personal protective gear started to be employed and I believe that consisted of full-face respirators and TYVEK protective gear.

* * * *

Q If you would, take a quick look at what we identified as Schecter Exhibit 6 and look at paragraph seven on page three.

A (Witness complies)

Q Did Mr. Joiner tell you that sometime at or about 1983, he would have learned about the contamination of the mineral oil, in some instances, with PCBs?

A I believe he said somewhere in the mid-'80s.

Q Is paragraph seven consistent with what he told you?

A Yes, it is.

* * * *

[46]

Q Did you review any of the medical records in Mr. Joiner's medical records where he had given his smoking history to his various treating physicians?

A Well, yes, I reviewed the material you and I looked at a few minutes ago.

Q Do you recall if what Mr. Joiner told you seemed to be consistent with his medical records?

A It seemed more or less consistent. As I understand from the deposition, there may have been a few areas where there was some disagreement as to when some doctors thought he had told them he had stopped smoking.

Q But in terms of what he had told you, did you think that what Mr. Joiner told you was consistent with the medical records? [47]

A It seemed to be.

* * * *

[49]

Q Setting aside the deposition for a moment, what do you recall he told you as an MD who was asking questions about his medical and smoking history? [50]

A I recall that he came from a family of smokers. He smoked many years. He gave up smoking. He had other chemical exposures and he came down with lung cancer. That's how I saw it as an MD. And he did not have asbestos or radon exposure.

* * * *

Q In terms of determining in your scientific methodology whether the chemotherapy may or may not have affected the level of PCBs, furans and dioxins in his adipose tissue, wouldn't it be

important to know what kind of chemotherapy was used?

A Well, as we mentioned earlier, there is no data at all on any type of alternations of dioxins, dibenzofurans or PCBs that I recall in published literature relating to specific [51] chemotherapy or radiation therapy or cancer therapy of any kind. The end result is thought to be — the end result of relevance is thought to be the weight loss or gain, although that may not be correct. Mr. Joiner and Mr. Warshauer told me or indicated that he had lost something like 30 pounds of weight and that he had subsequently gained or regained the weight, so there was — I had no reason to believe that I was not being told the correct information or truthful information. And so, there was a history of weight loss and then regain.

* * * *

[60]

Q Based on what you've learned in this case, what chemicals has Mr. Joiner been exposed to potentially?

A What stands out after the cigarette smoke is the PCB transformer fluids and the PCB, dioxin and dibenzofuran contamination. And when I say dioxin and dibenzofuran, I'm referring to chemical contaminants or breakdown products which are frequently found in PCB fluids or in transformer fluids. [61]

Q Any other chemicals that Mr. Joiner was exposed to?

A Not that I know of or that I can recall at this time.

Q Now, tell us what opinions you have reached in this case.

A I believe more likely than not that Mr. Joiner's lung cancer was causally linked to cigarette smoking and PCB exposure. And by PCB exposure, I'm thinking also of PCBs and dioxins and dibenzofurans and related chemicals which frequently are found together in transformer fluids.

Q Any other opinion?

A Well, that Mr. Joiner more likely than not has had a higher exposure or more exposure to transformer fluids and the chemicals in them than the average person, and this would include the PCBs, dioxins and dibenzofurans and related chemicals. And it seems to me from the history he's given, that until the mid-1980s, he was not aware of the fact that he was dealing with toxic chemicals and did not protect himself, nor did anyone attempt to protect him or inform him that he should be protected from these toxic chemicals. And this, of course, is a [62] breach of good occupational medicine or

industrial hygiene practice.

* * * *

Q Do you need any additional information in order for you to express these opinions?

A Not that I can think of at this time.

Q So, would these be considered your final opinions in this case?

A Well, if there is further information that would alter them, then they might not be final. I don't hesitate in coming to these conclusions at this time. They seem to be reasonable.

Q Do you plan any further investigation?

A I haven't really thought about that.

Q So, you've given no thought to any [63] additional investigation?

A Well, I would think that if this isn't settled in a reasonable fashion and goes to trial, then one might want to be a little more thorough with Mr. Joiner, although I think I've covered the major basis more than adequately. And —

Q You mean more thorough with his medical history?

A Well, I might want to do a somewhat more thorough medical evaluations, although at this time, I really do not see the need for it. And I might want to visit the site of his employment and look at the transformers, look at the room involved, but I might want to examine medical regards in more depth, although I don't see any point in examining the types of chemotherapeutic agents and their pharmacologic actions. I have sufficient knowledge for my purposes to know whether it would affect — know or not know as best anyone knows, how they might affect dioxin, dibenzofuran or PCB levels.

* * * *

[65]

Q Now, let's talk about your first opinion about the causal link. What facts do you base your opinion on that it's more likely than not that Robert Joiner's lung cancer is causally linked to cigarette smoking and exposure to PCBs and furans and dioxins, what facts is that opinion based on?

A Most lung cancer in the United States is caused by cigarette smoking. And with cigarette smoking in the presence of other carcinogens, for example, asbestos or radiation, the rate of lung cancer will go up markedly. PCBs, dioxins and dibenzofurans are definitely promoters of cancer, that is, once a cell has been initiated, once the cancer has been initiated in the cell, then these chemicals definitely will promote the cancer. In **[66]** addition, in animal experiments by themselves, dioxins, dibenzofurans and PCBs cause cancer in a dose-dependent fashion. We can probably leave it there unless you want me to elaborate.

Q Now, when you say that PCBs, dioxins and furans are definitely promoters, is that based on animal studies?

A That these cause cancer is animal and human study. That they are promoters is based on in vivo and in vitro studies. The in vivo studies in animals show that these chemicals alone or following dosing with initiators of cancer will cause increase in cancers. The toxicity is also studying for these chemicals by a number of biochemicals means such as enzyme induction. And recent work such as that of Dr. George Lucier and colleagues at the National Institute of Health have shown that humans — human tissue appears to be as responsible as animal tissue to these chemicals, as laboratory rats, for example, which are sensitive species. The human studies are studies such as the Yusho poisoning where an excess of cancer has been shown in some studies. And Dr. Fingerhut's NIOSH study, some Seveso studies where humans were exposed to dioxins as published by **[67]** Dr. Bertazzi and others, IARC studies, International Agency [for Research] on Cancer at the World Health Organization showing an increase in cancer in dioxin-exposed subjects and others.

Q I want to go back. When you used the term promoter, are you talking about strictly animal studies?

A These chemicals are considered a promoter based on evidence from laboratory studies.

Q On animals?

A On animals — primarily animal studies, yes.

Q Whose studies are you relying on?

A Many studies including that of Lucier and colleague. The studies I found, for example, many of them in the agency for toxic substances and disease registry toxicological profiles or PCBs and separate study or publication rather for dioxins and the separate

publication for dibenzofurans where they've attempted to catalog the majority of the studies which strongly show that these chemicals are very powerful promoters.

Q Again in animal studies, correct?

A The — well, by animal studies, are you **[68]** excluding humans as animals?

Q Yes.

A. You are refer to laboratory animals?

Q Yes.

A The studies for promoters per se have been primarily to date in animal studies. But human tissue has also been used for some studies of these chemicals and humans have been studied after exposure to the chemicals. But the difference is that we don't have the clear[ance] legally in this country to dose humans with toxic chemicals. The animal studies are far [more] powerful than the epidemiology studies where the sample size is smaller. We do not dose deliberately, so the dose is not known. The dose may be small. And latency periods cannot be followed as well as they can from animal studies or cell culture studies.

Q Again, your opinion that PCBs, dioxins and furans operate as promoters is based upon studies of laboratory animals only, is that true?

A The studies which tell us that PCBs, dioxins, and dibenzofurans are promoters of cancer were developed through laboratory animals and we have belief that they are relevant to humans. We **[69]** test them on animals. We believe that's relevant to humans.

Q Your opinion about PCBs, dioxins and furans being promoters is based upon studies of laboratory animals?

A Yes. And my reason for believing this is relevant to human studies is because all government agencies concerned with health believe that this is the case and that we can usually pre-detect, because humans also are in the animal kingdom. Human cells are nuclei, cytoplasm, mitochodria, endoplasmic reticulum and respond in similar fashion.

Q Object to the non-responsiveness to the answer after the word yes.

A I would object to your keeping — stating that laboratory animals are different from human animals. I believe that we are in the same kingdom. That's what I've been taught. That's what I

teach my medical students. We do teach them that what is in animals is related to human.

Q Object to the non-responsiveness. Now, is it your opinion that cigarette smoking was the initiator of Robert Joiner's lung cancer? [70]

A Well, that's an interesting question. We, of course, do not know whether the PCBs, dioxins and dibenzofurans also serve in an initiation function. One might — I would think that the cigarettes probably served as initiators and that the PCBs, dibenzofurans and dioxins probably more likely than not served as promoters of cancer. They may, in addition, also have served as initiators. These words aren't magical. They simply refer to whether the DNA is directly attacked or not.

* * * *

[71]

Q Based on your study in this area, what occurs when you administer the PCBs before the administration of the initiator in laboratory animal studies?

A As I mentioned previously, PCBs alone also cause cancer, and this has been shown in many studies. They do not need to be — to have a promoter given first. So that PCBs, dioxins and dibenzofurans have been described as complete carcinogens by Dr. James Huff of the National Institute of Health because when given alone they will cause cancer to laboratory animals and probably to humans.

Q Now, which chemicals are you speaking of there?

A I'm speaking of dioxin and dioxin analogs which would include dibenzofurans, PCBs and other structurally very similar chemicals.

* * * *

[72]

Q Did I understand you to say that this is all dose dependent?

A These chemicals cause cancer in a dose dependent fashion.

Q What is your understanding of the term dose dependent?

A That means in simple language, the more you give, the more toxic outcome you get.

Q Does it also mean that there is a threshold over which the chemical must reach in order to have any toxic effects?

A No. As Dr. George Lucier and . . . Angelika Tritscher, George Clark and others have shown, a threshold is not implied nor is it necessarily found on biochemical responses with these chemicals.

* * * *

[75]

Q Let's move to your second opinion which was that in your opinion, Robert Joiner had higher exposure than the average person to PCBs, dioxins and furans. On what facts do you base that opinion?

A The fact that he worked with these chemicals.

Q What other facts?

A The fact that he worked with these chemicals for many years, he handled PCB contaminated transformer oil, he breathed smoke, he was in an underground enclosed area with no [76] protective gear for years. The rest of us do not normally handle chemicals contaminated with PCBs, dioxins or dibenzofurans as part of our work. That's not part of the work of the major population.

Q What other facts do you base your opinion on?

A Those are essentially the facts that I base them on, as I do normally in the practice of occupational medicine.

Q Are there any other facts on which you can think of on which you base that opinion?

A The documents we've discussed, my interviews with the patient and his wife, documents provided me by Mr. Warshauer and his colleagues. . . . And I would perhaps even go a bit beyond that. I think it would be of less consideration than the others opinion which usually a physician would come to the conclusion, the ones I've just given you. But the fact that this patient had a four-tenths — 0.4 parts per million of total PCBs in his adipose tissue despite cancer chemotherapy, weight loss, weight gain after the exposure without protection and without customary protection against [77] toxic chemicals such as PCBs, dioxins and dibenzofurans, despite the fact that he still had 0.4 part per million of PCBs suggests to me that this is additional comf[i]rmatory evidence for exposure beyond that of the average. Which we know he had because of his job.

Q How many years did you assume Robert Joiner was exposed

to PCBs, dioxins and furans?

A I believe his exposure started on or about 1973, when I believe he started in the work, and continued at least until he began to wear protective gear and probably decreased in an amount — the protective gear was after that time in the mid-'80s.

* * * *

[78]

Q Looking at the affidavit of Robert Joiner, did you assume based on his affidavit that he would have had roughly ten years of exposure without the use of any protective equipment?

A Well, if he started in 1973 and somewhere after ten years began to wear protective equipment, I assume that he had exposure during those unprotected years.

Q Now, during those unprotected years, how do you quantify his level of exposure?

A There is no way of quantifying what has entered his lungs which is where he got the cancer and where it is the site of PCB metabolites. This is where PCB metabolites congregate and deposit. I assume that — it seems highly logical to me that he breathed PCBs, dibenzofurans and dioxins and so, there was an immediate passage through the lung [79] cells and to a certain extent deposition. We have no way of quantifying dose and target organ from that kind of exposure. There is no method that I know of published in the medical literature which would allow us to do that.

Q So, you have no opinion as to the level of PCB, dioxins or furans in Mr. Joiner's lungs?

A I have an opinion that it is above that which the general population would be exposed to.

Q But again, you cannot quantify that, can you?

A The exact amount, no, I cannot quantify the exact amount.

* * * *

[84]

Q What information do you have about the concentrations of PCBs, furans and dioxins in the mineral oil contained in the transformers that Robert Joiner worked around?

A We have specific data back that came by fax yesterday, and I showed you my entire file, showing that there were PCBs in some

of the mineral oil. And my general knowledge that dibenzofurans and dioxins are found in PCB-containing electrical transformer oils.

* * * *

[85]

Q What was the level of concentration?

A It varied from a few parts per million up to a few hundred parts per million in those that I looked at that came in yesterday.

Q Do you recall seeing any that were greater than a few hundred parts per million?

A I don't remember. I didn't look at every page.

Q Did you see any record that indicated any of these transformers contained pure Aroclor?

A No, I did not.

* * * *

[97]

Q Is direct tissue measurement of PCB, furan and dioxin levels in the human body from a fat biopsy preferable than a clinical history? It's better to have the fat biopsy than it is to take a clinical history from a patient for determining the measurement of PCBs, furans and dioxin in the human body?

A Well, for determining whether there is an exposure, it seems to me you are asking one question and applying the second. Maybe I'm wrong. If I am, please correct me.

If you are asking me how do I determine the amount of dioxins, dibenzofurans or PCBs in longer liver or adipose tissue. The only way in doing that, of course, is to measure it.

If, on the other hand, you are asking me as a physician can I come to a conclusion about whether a person has a higher intake than average or normal or that he or she would have otherwise by other means, and would I more usually use other means, then I would say sure. Usually physicians use other means. As you well know, Svenson & Rappee [98] in the Journal of Medicine. The fish were contaminated and when they measured the people's blood, the people's blood was also contaminated. The levels were higher in the fish. They were higher in the people. Did they do a $2,000 test on the person? Of course not. If the people ate the fish, of course, they had a higher intake. No insurance company in America would probably pay for a dioxin blood test. They would

think I as a physician would take a leave of my senses in ordering such an unusual test that's not considered anything other than a research technique at this time and is unnecessary to establish the clinical impression.

* * * *

[107]

Q As far as your methodology in reaching your opinion today, have you made an effort for determining the half-lives for specific congeners that were found in Robert Joiner?

A Of PCBs?

Q And furans and dioxins.

A I believe I summarized for you a few minutes ago what we know about dioxins and dibenzofurans half-life of secretion in healthy **[108]** adult human beings in our previous conversation. Do you want me to repeat that?

Q The question I asked you was: In your methodology in reaching the opinions that you have expressed today, did you make an effort to go back from scientific literature and determine the half-lives for the congeners that were found in Robert Joiner? Either you did or you didn't.

A What I don't understand is several things. My methodology for doing what?

Q Reaching your opinion.

A On what? Which opinion? We went over a number of opinions.

Q We have three opinions that you expressed. That he had a higher exposure than the average person. That there was some causal link, and you talked about when he had told you that he may have been aware that there was some contamination in some of the transformers. Now, those were your three opinions. My question is on your opinion about higher exposure, in your opinion about the causal linking that you reached in your opinion, in the scientific methodology that you used in reaching those two opinions, did you look at the **[109]** scientific literature to determine the half-life of any of the congeners found in Robert Joiner's adipose tissue? Either you did or you didn't.

A In the past year, I reviewed the literature for half-lives of PCBs, dioxins and dibenzofurans as a peer reviewer for the US Government on the dioxin and the dibenzofuran and separately the

PCB toxicological profile. I reviewed those and have those as part of my general knowledge. For the dibenzofurans and dioxins, the information appears to be better. They were part of my general knowledge which participated in my coming to conclusions.

* * * *

[112]

Q Now, are you aware of any animal studies that have been done on mice that would suggest that PCBs are a potent anti-carcinogenic agent? **[113]**

A There are studies which would show — which found less tumors of a certain kind in animals exposed to PCBs or to dioxins than in controlled animals under the circumstances of the experiment.

Q In other words, instead of being a promoter, it was an inhibitor?

A That could be one interpretation. Another interpretation is that it's a statistical fluke. The sample size was inadequate — this is something that's been considered and studied in many laboratories.

* * * *

Q Isn't it true that in your personal library that you have a container where you have collected a number of Dr. Safe's articles? **[114]**

A I've tried to collect most articles written about dioxins, dibenzofurans or PCBs.

* * * *

Q Do you agree that laboratory studies have established that the paralysis of chlorobenzene at temperatures of at least 600 degrees centigrade will yield dioxins and furans? **[115]**

A Yes. And they've also established it at lower temperatures.

Q How much lower?

A Well, that's a subject of debate. Incinerators seem to be producing it as the temperature goes lower on the way out. But that's certainly been well-documented.

Q Do you agree that laboratory studies have studies that for

paralysis of PCBs again you have to have temperatures of at least 600 degrees centigrade to produce furans?

A No. Your statement is not correct.

Q What minimum temperature is necessary?

A I don't know the minimum temperature, but in 200 to 600 degrees, you get a yield of PCBs being empirically converted to a reasonable larger yield of dibenzofurans and a somewhat smaller of chlorinated dioxins and the chlorinated benzenes of which you spoke previously. Again, in the 200 to 600 degree centigrade temperature will produce a yield to greater or lesser extent of chlorinated dioxins and/or dibenzofurans.

Q Now, in your scientific methodology in reaching your opinion, have you looked at any **[116]** scientific articles to determine the minimum temperature necessary when heating PCBs to create furans or dioxins?

A Yeah. I've talked to the people who published the articles and done the research, Keith Keesolie who showed that municipal incinerators produced de novo dioxins and dibenzofurans which did not exist in the household garbage being burned.

* * * *

[123]

Q Are there any human epidemiological studies that in your opinion support the opinions that you have reached in this case that PCBs were a promoter of lung cancer?

A The human studies I don't think focus the — quite so much on promoter versus initiator as to was there cancer and was there death due to cancer. In support of that, it seems to be reasonable to cite the study which frequently is cited which was performed by Kuratsune and colleagues in Japan where he found an increase in liver and lung cancer of — and cancer of the respiratory tract in some of the rice oil poisoned patients which were exposed to PCBs and dioxins and dibenzofurans. And he pointed out that in one geographical region, the cancer mortality was higher than the second geographical region, although the exposure was to people who lived in both areas.

And one possible explanation for this is that these were promoting the cancer formation and that there were other chemicals which were more prevalent in the people who lived in the geographical area where there was more cancer seen. This was one

of the studies that's cited for PCB and **[124]** dibenzofuran human promotion.

Q Other than Kuratsune, are there any other human epidemiological studies on which you rely in support of your opinions in this case?

A Well, I mean, there are human studies for cancer. Are you saying that the mechanisms be promotion only?

Q I took promotion out of the question.

A I understand you to be asking me broadly.

Q Correct.

A Yeah. I would cite the early human studies that suggested that this class of chemicals causes cancer in humans, leaving out the capacitor manufacturing cancer studies entirely. I would go to Hardell and colleagues on the chloracne and phemoxyherbicide exposed Swedish workers with an increase in certain kinds of cancer. Then I would — where he made the assumption that most likely the dioxin contaminants were one of the major ideologic factors.

The next series of studies that comes to mind would be the Fingerhut study that we mentioned for dioxin exposed to American workers, done by NIOSH, US Government Agency and then the IARC study, **[125]** International Agency on Research and Cancer, which is part of the World Health Organization, with an excess in cancer mortality and dioxin-exposed workers from a number of countries.

The next study I would think of would be the Zober study from Germany. The next study I would think of would be Thiess, more or less the same finding. German workers increase in gastrointestinal cancer when matched to suitable control group, dioxin-exposed workers. And Manz study on European workers exposed to dioxin with an excess of cancer death as compared to controls. And last, the Seveso studies with excess cancer mortality from — done by Bertazzi and colleagues.

Q That was the capacitor study, wasn't it?

A Yeah.

Q I thought you were going to leave those out?

A I was for the moment not focusing on the capacitor study. There are a series of those, as well, suggesting that PCB exposed capacitor workers may have an excess mortality. I was thinking instead of the Bertazzi dioxin exposed. I'm making the assumption

that dioxins, dibenzofurans are [126] structurally very similar and they appear to work in the human body for the most part, in going to the same receptor and cytoplasm and complex, going into the nucleus and starting everything off in this toxic cascade that we have very well characterized in animals and are increasingly characterized in humans.

* * * *

[127]

Q Was Mr. Joiner's level of dioxin found by Triangle laboratory well below background levels?

A Triangle Laboratory had a major problem for doing this. I give no credence to their results. They are not a World Health Organization. They did not take part in this round robin tests. And in any good laboratory result in human tissue, you should at least have a recognizable level for each of the 16 usually reported dioxins or dibenzofurans, and usually they had nondetect[able]. Which to me indicated they had a great deal of trouble in laboratory methodology.

Q Let me object to the responsiveness of the answer and ask the question again.

Wasn't the level of dioxin found in Robert Joiner's adipose tissue sample by Triangle Laboratories lower than the general background level? Either it was or wasn't.

* * * *

[128]

A My answer is garbage in, garbage out. They obviously have major problems with that laboratory analysis and I was a physician who is very experienced in that field and can give it no credence whatsoever.

Q Was the number which was reported below background levels?

A If the lab obviously had a major methodologic problem, I wouldn't use that in coming to a conclusion.

As we mentioned earlier, we described the numbers that I think are average for the United States, but that means you get results, you have a good lab doing good results. And as you know, the label error for dioxin laboratories is subsequently generally about 25 to 40 percent plus or minus. But you should have a number.

You shouldn't have nondetect[able].

* * * *

[130]

Q Do you know of any animal studies on respiratory effect in laboratory animals after inhalation exposure to PCBs, dioxins or furans?

A There are very few, if any, laboratory tests that have been done on animals with respect to respiratory toxicology of dioxins, dibenzofurans and PCBs. And I do not remember the content of the section on respiratory toxicology and the toxicologic profiles which I reviewed in the last year. I don't recall that at this point, if there [131] were any. I know that they are extremely sparse, if any.

Q For respiratory effects in general?

A No, for intake of the chemicals through the body. You can have intake through the gastrointestinal tract or the skin or the lungs. And if the chemicals then go throughout the body to the lungs or other parts of the respiratory system, you can and will have in some cases toxic effect in the target organ even though the chemical has come into the body and then gone into the target organ through the blood, regardless of the routes of entry.

Q Do you know of any animal studies on cancer in laboratory animals after inhalation of exposure of PCBs?

A I don't recall any at this time.

Q Do you agree that controversy still exists concerning animal studies and the quantitative relation between dioxin exposure and their possible toxic effect on humans and that those have not been sufficiently established?

A Any scientist will always conclude that further research would be of value. That's the way [132] we make our living and the way we make the world more certain. On the other hand, after the recent results in Lucier's lab, I think we have moved massively forward in understanding the relation between the levels which cause illness in animals and classically studied animals and human tissue responsiveness. We're moving markedly forward on the quantitative side.

* * * *

[157]

Q For General Electric Company, Westinghouse Company and Monsanto Company, was it ever said to you that laboratory results such as the ones that were performed by Triangle Laboratories on Mr. John Samples (six), that Triangle was not good for doing such laboratory work?

A I don't recall anyone saying that. I base my opinion on the fact that Triangle Laboratories did not take part in nor get certified [158] by the World Health Organization in interlaboratory validation studies for human tissue in either of the two round robin studies that have been conducted nor to the — those are the only two that I know of. And plus the fact that those results are completely unbelievable and in the practicing medicine, when you get back a result which is obviously off the wall, bears no resemblance [to] what you expect to see from a living human being, then you reject it and say there is something wrong in the lab. That happens 10 or 20 percent of [the] time in medicine.

* * * *

[169]

Q Are you saying that he came into contact to these PCBs through ingestion, dermal contact or breathing of vapors?

A By ingestion, gastrointestinal tract?

Q Yes.

A It would seem to me that he ate food without necessarily cleaning his hands and the food almost certainly on some occasions was contaminated with an excess of PCBs and dioxins and dibenzofurans from his job. And number two, he breathed without protective gear. Heated and unheated transformer [170] oil which, in some cases was contaminated with PCBs, and if PCBs, almost certainly dibenzofurans and dioxins. And third, he did not protect his skin from that, so his hands and face and neck and shoes and feet almost certainly got some transformer oil.

Q You are saying all three?

A Yes.

Q How much, can you give us any idea of quantity? Is it 1 percent more than the general population or 100 percent more or how much?

A I don't think it 's scientifically possible to come up with a good estimate, and particularly with respect to the target organ that

we're most concerned with, how much got into the lung.

Q Now, you've also said that the Triangle Lab report which showed his body burden —

A Which did not show his body burden.

Q You said it was defective. How was that test ordered?

A I have no idea.

Q You said that as a scientific — when you see a test you don't think is reliable, you repeat it or you ignore it? [171]

A Well, as a physician. First of all, I happen to be one of the people, the physician scientist who develops this kind of testing in humans in America. And so, I have a fair amount of experience as to when this looks believable and when I tell a chemist, you guys have goofed.

* * * *

[176]

Q Doctor, I just have a few more questions I'd like to ask following up about your scientific methodology.

As part of your opinion, are you assuming that the heating of the transformer cores created furans or dioxins, are you assuming that?

A I'm assuming that where PCBs were present, and they were present in some of these cores, I believe there probably was a certain degree of formation of dibenzofurans and dibenzo — dioxins. I'm also assuming that in general, it's my understanding of what we know in the field that as PCB containing transformer fluids are used, that there is a certain chemical change of PCBs and an increase in dibenzofurans and to a lesser extent dioxins.

Q But did I understand you to say you don't know the temperature that's necessary, the minimum temperature that's necessary to create furans and dioxins from the heating of PCBs, you don't know that number, do you?

A I don't recall what the lowest published [177] number at this point is and as I told you, it's my understanding of the literature that it's still an active topic of scientific chemical-type research as to what the lowest level would be. I don't think it's so much in doubt that PCB containing transformer oils do usually contain dibenzofurans in normal. I think that's well established. I believe it's fairly well established that there is a gradual increase of the dibenzofurans in PCB containing transformer oil.

DEPOSITION OF ROBERT K. JOINER

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

Deposition of Robert K. Joiner, taken in the above styled case on the 9th of June, 1993, in the County Commission Room of the Thomas County Courthouse, North Jackson Street, Thomasville, Georgia; commencing at approximately 9:10 a.m., before Judy B. Scott, Certified Court Reporter B-1487, Georgia.

* * * *

[2]
Whereupon, ROBERT K. JOINER, having been produced and first duly sworn as a witness, testified as follows:

* * * *

[85]
Q When you were draining this oil, just give us an idea on these small transformers, the smallest you have, which you said was a 2.5 —
A Very few of those, though.
Q But you might have a lot of fives?
A We've got a lot of fives, tens.
Q How much oil would be in there?
[86]
A Depending on the age and the style it was made four to fifteen gallons.
Q Even in a five, four to fifteen?
A Well, not a five, no; four to ten, maybe.

Q And then on up to the larger transformers, what type of volume capacity are we talking about?
A You're looking at literally hundreds of gallons.

* * * *

[100]
Q Now, prior to 1985 or '87, whatever that year is, there was simply no attempt to distinguish between a mineral oil or a PCB contaminated oil? You just treated them all as one and the same —
A Right.
Q — insofar as your physical contact with it?
A Right; I — no protection.
Q When did you first learn that there might be some problem with PCB in these oils?
A During all this changeover to put — give us protection.
Q Before that time, you did not know that?
A (Nodded in the negative.)
Q The City never gave you any information about it?
A (Nodded in the negative.)
Q So, at the time that the protective gear was furnished, that's the first time you had any realization that there could be some problem with contact with PCB?
A No, I cannot be sure of [the] exact dates.
Q Did you know you were working on transformers that had oils in them that could be PCB contaminated?
A Prior to that?
Q Yes, sir.
A (Nodded in the negative.)

[101]
Q You didn't know anything about that?
A (Nodded in the negative.)

* * * *

[189]
Q Now, you said there were two fires in the '70s in substations involving voltage regulators. Do you remember that testimony?
A Yes.
Q And the oil that was in those two voltage regulators spilled out and was ignited?

A Correct.
Q Who extinguished the fire, those two fires?
A We did, with a fire extinguisher.
Q Did you wear any sort of protective gear?
A None.

[190]

Q And the fire department was not called?
A Yes.
Q Did they assist in extinguishing the fire?
A We used their extinguisher.
Q Was the fire department there at the time?
A Yes.
Q Did they offer to you any of their protective equipment?
A No.
Q How long did it take you to extinguish those two fires?
A Ten minutes or fifteen. The smoke bellowed for a good while, but —
Q Now, in the substation, what else would have burnt in addition to the fluid that was in the voltage regulator?
A What do you mean; other associated equipment?
Q Yes.
A It burned the paint off of one regulator beside it and smutted up a few items. but it mainly contained to one regulator.
Q Anything that you can recollect that was burnt, other than the regulator and the paint on the regulator?
A The regulator was — the paint was burnt completely off. It destroyed the control cabinet on the front; it was burnt completely up.

[191]

Q Do you know how much fluid was actually contained in those two regulators? I'm not sure how — how much fluid are we talking about?
A Probably between 80 to 90 gallons per regulator.

* * * *

[200]

Q Back in the mid '80s, were you ever given anything to read about PCB contamination or PCB's, by either the Water and Light Department or MEAG or the EPA?

A Not MEAG; it wouldn't have anything to do with it.
Q Or EPA?
A I don't know what year it was when we started getting information. I just don't know.
Q And was there a period of time where there started to be posted notices around your work area as well?
A When I got sick.
Q Before that, they never posted anything at the [201] Water and Light Department?
A (Nodded in the negative.)

* * * *

[202]

Q Now, did your — most of the time — well, did you ever have nay problem with your nose or your throat burning when there was smoke?
A Uh-huh (affirmative response), correct; yes.
Q Was that just some of the time, but most of the time you didn't have the problem?
A Some of the time depending on how much smoke was available from baking.

[236]

Q Did you ever receive any information from Monsanto advising you that there were contaminants in PCB's, including polychlorinated dibenzofurans —
A No.
Q — and then trichlorinated dibenzodioxins that could be hazardous to your health?
A No.

* * * *

Q And did you ever receive any information from G.E. or Westinghouse that their mineral oil transformers had PCB contamination in them?
A No.

DEPOSITION OF
DR. WILLIAM CHARLES BAILEY

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

The deposition of DR. WILLIAM CHARLES BAILEY, taken pursuant to Notice and agreement of counsel and pursuant to the Federal Rules of Civil Procedure and the Federal reading and signing of the deposition; before Robin B. Myers, Certified Court Reporter and Notary Public in and for the State of Georgia; commencing at 9:05 a.m., Friday, October 29, 1993 at 1600 The Candler Building, 127 Peachtree Street, Atlanta, Georgia

* * * *

[4]

Whereupon,

DR. WILLIAM CHARLES BAILEY
was called as a witness herein and, having been first duly sworn, was examined and deposed as follows:

[8]

Q. What else do you have in your file relating to this case which you did not bring with you?

A. Well, you know, I don't have a file as such, but I reviewed all the medical records. I've got a two-volume set of medical records for the patient. I reviewed — I did a literature search about a year ago and then updated that, reviewed all the abstracts and

selected — and articles that related to PCB and human disease and everything I could find in the literature, plus the — these other attorneys had sent me a few articles, most of — some of which were actually duplicates of things that I'd found in — in my review of the literature initially. And then I did that again just about a month or so ago just to see if there was anything I had missed. I've got a couple of other ones there, reviewed all those, and just kind of generally reviewed the literature once again in the whole area of — of lung cancer, small cell carcinoma, specifically, and smoking-related problems and those represent sort of the — some things that I thought were pertinent to the particular issues at hand.

[9]

Q. How about depositions?

A. Yeah, now, actually that's right. I had a deposition from Arnold Schecter and a deposition from the — the patient and a deposition from a toxicologist from the University of Kentucky, Robertson, I think.

Q. Anybody else?

A. And the patient . . . . I think those were the only three depositions that I reviewed.

Q. Did you review anybody's summaries of depositions or did you review the actual deposition?

A. I reviewed the actual deposition.

Q. Did you actually read them?

A. Uh-huh (affirmative), yes.

Q. With respect to the medical records, did you actually read them or have someone review them for you and —

A. I believe I actually read those. Now, they were organized by somebody in terms of just Xeroxed and put together in a — in a two-volume set.

[11]

Q. How much time have you devoted to this particular case?

A. I would guess probably about 20 hours, something like that. I haven't really counted them up, reviewing all the data, primarily.

* * * *

Q. Do you have any written notes of any kind that outline your opinions or thoughts on this case?

A. No, I haven't written anything out. I've just reviewed a lot of literature and come to some [12] conclusions, but the conclusions were fairly straightforward.

[25]

Q. I had asked you earlier whether you had done any — if any of your recent writings had had anything to do with PCB exposure. I couldn't find any of your past writings to deal with any — to have anything to do with PCB exposure; am I correct?

A. That's right. I have never written anything about PCB exposure.

Q. And I'm also correct you've done no hands-on research in the field?

A. That's right.

Q. And that would include dioxins and furans?

A. Uh-huh (affirmative).

Q. Try to answer yes or no.

A. Yes.

[37]

Q. Tell me which articles that you have reviewed that you think are the leading articles in this field of PCBs that relate to the subject about which you are going testify.

A. Well, you know, I just don't have the articles at hand to really remember the specific authors of the different ones. I just reviewed all of them sort of in toto.

DEPOSITION OF WILLIAM J. WADDELL, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

The deposition of WILLIAM J. WADDELL, M.D., taken pursuant to Notice and agreement for cross-examination, discovery and any other purpose allowed by law and pursuant to the Federal Rules of Civil Procedure and the Federal Rules of Evidence; all formalities waived, including the reading and signing of the deposition; before Joyce S. Oglesby, Certified Court Reporter and Notary Public in and for the State of Georgia; commencing at 10:10 a.m., Tuesday, October 19, 1993 at 4000 One Peachtree Center, 303 Peachtree Street, Atlanta, Georgia.

* * * *

[4]

(Witness sworn.)

Whereupon, WILLIAM J. WADDELL, M.D., was called as a witness herein and, having been first duly sworn, was examined and deposed as follows:

* * * *

[30]

Q. You used animals as the group within which to study human carcinogens; is that correct?

A. That's correct.

Q. Did you think that was a scientifically valid method of study of these human carcinogens?

A. Well, it's the only way we can study humans, the kind of studies that I was doing because it's [31] unethical to do to humans what I did to the mice.

Q. Were the mice sacrificed?
A. Yes.
Q. Were the mice injected with known carcinogens?
A. Yes.
Q. And did you do this in order to extrapolate information from the mice's reaction to these injections so that you could extrapolate that information to humans, or did you do this just to see what happens to mice like my kid does with a magnifying glass and crickets?
MR. FLINT: Your kid does what?
MR. FREEMAN: That is hereditary.
BY MR. WARSHAUER: (Resuming)
Q. Do you know what I'm talking about?
A. Yeah, I know what you're talking about.
Obviously, the — the species of ultimate interest is the human, and we do things in experimental animals to see if we can gather any kind of information with which we can extrapolate to humans.
Q. Is that accepted in the scientific community to follow that procedure?
A. The procedure is to get all the information we can. We cannot extrapolate directly from experimental animals to humans, and that's why we do several species [32] and different strains, and we do all kinds of — If there was an acceptable animal species which responded just as a human, that's what we would all be using. But since there is none, we have to do what we can to do — get the information possible.
Q. But does the information have value with respect to humans?
A. Sometimes it does, and sometimes it does not.
Q. Within the scientific community, would you agree that the purpose of studies on animals is to be able to get information which can or may be extrapolated in humans?
A. That's the purpose.
Q. And that methodology of using animals is, in fact, scientifically accepted in the community as a whole?
A. The method is accepted — is accepted and is appropriate and proper, but the information cannot be blindly extrapolated to humans. It must be extrapolated with great caution.
Q. But the method of extrapolation, the process and the

practice —
A. The process —
Q. — of extrapolation is part of the [33] generally-accepted scientific methodology used here in the United States and in the world?
A. Of course.

[77]
Q. Now, we talked a little bit about the studies of PCBs on various animals. Do you think it would be appropriate to study PCBs on humans, not people who've already been exposed, but give them a dose, follow them along?
A. What would be the purpose of the study?
Q. To see what happens, I guess. What was the [78] purpose of your taking phenobarbital?
A. Well, I had a — I had a specific purpose, experimental design in mind, and I guess I'd have to know what the specific experimental design — what's —
Q. To see whether they get lung cancer.
A. That's unethical to give anyone something to see if it produces a carcinoma. That's unethical; I don't care what it is.

[113]
Q. Have you been provided with a copy of Dr. Teitelbaum's deposition?
A. No, I haven't.
Q. Are you aware of his opinions?
A. Not really, not —

[116]
Q. Did you read Dr. Schecter's deposition?
A. I read the excerpts prepared by Teitelbaum's staff.
Q. What did you think of his thoughts?
A. Well, I — I completely disagreed with his interpretation of what happens when you lose body fat. I think he's just going in exactly the wrong direction, and I think all the scientific information will back me up on that.
Q. What about his other opinions, that PCBs are not good for humans and nor are furans or dioxins?
A. I think he's exaggerating the information we have available.

DEPOSITION OF DR. PHILIP COLE

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

The deposition of DR. PHILIP COLE, taken pursuant to Notice and agreement for cross-examination, discovery and any other purpose allowed by law and pursuant to the Federal Rules of Civil Procedure and the Federal Rules of Evidence; all formalities waived, excluding the reading and signing of the deposition; before Joyce S. Oglesby, Certified Court Reporter and Notary Public in and for the State of Georgia; commencing at 12:10 p.m., Thursday, October 21, 1993 at 4000 One Peachtree Center, 303 Peachtree Street, Atlanta, Georgia.

* * * *

[4]

(Witness sworn.)

Whereupon, DR. PHILIP COLE was called as a witness herein and, having been first duly sworn, was examined and deposed as follows:

* * * *

[8]

Q. With respect to the medical records, did you mark them, tab them or otherwise notate them in any fashion?

A. I did not.

Q. Did you make any notes regarding them?

A. Yes, I did.

Q. Did you bring those with you?

A. They would — The ones that I considered the most important would've been incorporated into a sheet that I have that

represents that information and some other information as well.

[11]

Q. I'm going to show you Plaintiffs' Exhibit No. 5 which you have another eight-and-a-half-by-eleven sheet that says, "PCBs and Cancer: A Summary of the Literature." What is that, sir?

A. This is a tabulation of some of the results from a series of studies that have been done on people who are exposed to PCBs in the course of their work.

Q. Who did that?

A. I did.

Q. Did you read all of those studies?

A. Yes, sir.

[15]

Q. Are there any other documents that you have reviewed specifically and prepared specifically for this particular case?

A. I have read some other documents, yes.

Q. Which are the ones that come to mind as being most significant to this case?

A. Most significant?

Q. That's right.

A. I read the deposition of Mr. Joiner.

Q. Do you have that in your file?

A. I have it in my file, but in my office. I did not bring it.

Q. So, in fact, Schecter, the medical records and Mr. Joiner's deposition?

A. Correct. That is correct.

[37]

Q. Have you ever read any of the materials concerning PCBs and furans and dioxins prepared by Arnold Schecter?

A. I — I haven't read anything of Dr. Schecter's, other than his deposition in this case.

[42]

Q. Would you agree that there are scientists who believe that animal studies can be used as indicators for human reaction to a particular carcinogen or to the potential carcinogen?

A. Indeed there are. I'm one of them myself.

[75]

Q. You mentioned that there's a list. Where would I go to find a list that you would recognize? I know you just work from memory, and you may have inadvertently included one that's not on the list or included one — failed to include one that is on the list. I accept that as a possibility. Where would I go to find a list that you would recognize?

A. First, let me tell you that I didn't mention one that would not be on the list.

Q. Okay.

A. But I certainly did fail to mention some that — that are on the list.

The list that I like best, which is not to say that I subscribe to it across the board, is the list of Class I carcinogens put forward by the International Agency for Research on Cancer.

Q. IARC?

A. Correct.

Q. Do you recognize that group as a group that [76] is — whose opinions on cancer should be given a certain amount of credibility?

A. Let me say that there is no such thing as that group. The IARC is, in the context of which we're speaking, a convening body. It is not a authoritative body in and of itself. So, if I change your — if I change your question to be, "Are the results of the workshop groups convened by the IARC generally to be accredited?" the answer's yes, generally.

[105]

Q. Are you a believer that secondhand smoke is in fact a significant cause of lung cancer?

A. If you don't mind, I don't like to call it secondhand smoke.

Q. ETS.

A. Some of it is firsthand. Some of it has not [106] been expired by someone else, but it's coming off the cigarette. ETS, oh, yes, indeed.

Q. And what studies do you rely on?

A. There are about six or eight studies on this question. I can't cite them for you, but I would mention to you that the august body of the EPA has come to the conclusion that ETS should be taken as a recognized human carcinogen for the lung.

DEPOSITION OF STEPHEN B. HAMILTON, JR.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

Deposition of Stephen B. Hamilton, Jr., taken on behalf of the plaintiff in the hereinbefore entitled action, pursuant to the Federal Rules of Civil Procedure, before Melanie G. Collard, RPR-CM, duly qualified Notary Public in and for the State of Connecticut, at the Trumbull Marriott, 180 Hawley Lane, Trumbull, Connecticut, commencing at 9:05 a.m. on Wednesday, July 28, 1993.

* * * *

[4]

STEPHEN B. HAMILTON, JR., 154 Driftwood Lane, Trumbull, Connecticut, 06611, having been duly sworn, was deposed and said:

MR. WARSHAUER: This will be the deposition of General Electric Corporation taken pursuant to notice. I understand corporate representative on a number of topics is going to be Stephen B. Hamilton Jr. This deposition is taken pursuant to that notice and by agreement. We can waive all formalities and reserve all objections except as to the form of the question responsive thereto until such time as the transcript is sought to be used. Is that agreeable?

MR. COCHRAN: Yes. He's designated specifically on the health effects of PCBs and PCB mixtures and on the history of

General Electric's knowledge about health effects and General Electric's research concerning PCBs.

MR. WARSHAUER: Okay. He'll reserve signature?

MR. COCHRAN: Yes, please.

* * * *

[13]

Q When did you first become involved in the PCB issue?

A In 1981.

Q And why is it that you became involved in the PCB issue at that time?

A I took a new position in the company in something called Corporate Environmental Issues Project, and I was given responsibilities related to PCBs.

Q Prior to 1981, you had had no activities in that [14] field?

A That's right.

Q Did you follow it at all?

A Only in a very peripheral way.

Q Such as you knew that they had stopped making askarel transformers, for example?

A I knew that, yes.

Q Had you kept up at all with any of the literature about health effects or environmental effects of PCBs or its contaminants which might be PCDDs or PCDFs?

A Not at that time.

Q Once you became involved in 1981, what were the steps that you took to familiarize yourself with the subject?

A I did a number of things. One was to work through the NEMA organization, to interview a number of consulting firms that could assess the literature and provide a report regarding their assessment of the literature related to PCB health effects.

[35]

Q Am I correct that you have far less experience in the PCDD issue because you do not believe that PCD — I meant PCDD, you have far less on the dioxin issue because you don't see that dioxins are a contaminant or potential result of a change to PCB mixtures

used in askarels?

A I think that dioxin is much less of an issue related to PCBs than PCBs are to dibenzofurans. I would not agree that it is impossible that askarels would lead to dibenzodioxins under certain conditions.

Q It's possible, it's just not much of an issue?

A It's possible, but it only occurs apparently in rather unusual circumstances.

[51]

Q Do you think that PCDFs pose health risks to humans?

A I believe that PCDFs pose potential health risks to humans, and that's primarily based on the Yusho — that's Japanese — and the Yucheng — that's Chinese — incidents, both of which involved contaminated rice oil consumption. I do not believe that PCBs as — I'm sorry — PCDFs as contained in PCBs in electrical applications pose any additional risks to humans.

[84]

Q All right. With respect to Plaintiff's Exhibit No. 1, do you recognize that document?

A Yes, I do.

Q What is it?

A It's a letter from me to a Dr. J. Donald Millar, who is the Director of NIOSH.

Q That is November of 1982?

A Yes.

Q Am I correct in summarizing that letter by saying you are complaining to him about his characterization of PCBs as probable carcinogens? What's the term he used exactly?

A Let's see. I'm complaining specifically about the statement in the Federal Register, and I quote, "In animals and humans, PCBs have been found to be carcinogenic," in addition to several other sloppy-type errors that surprised me and disturbed me.

[88]

Q Have you read any of Dr. Schecter's works on the subject of PCBs?

A I read some of his papers.

Q Do you have an opinion as to their scientific validity?

A I think the data is probably about as good as could be obtained. He's worked with a lot of analytical chemists that are well regarded.

Q Do you disagree with his analysis?

A I can't think of any specific cases where I do.

MR. WARSHAUER: I'm done.

DEPOSITION OF THOMAS O. ROUSE

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

EXAMINATION BEFORE TRIAL of the Defendant, GENERAL ELECTRIC COMPANY, taken by and through its representative, THOMAS O. ROUSE, held at the Desmond Americana, Albany-Shaker Road, Albany, New York on July 27, 1993, commencing at 9:10 a.m.; before Paula M. Marcucci, a Shorthand Reporter and Notary Public in and for the State of New York.

* * * *

[3]

MR. WARSHAUER: This is to be the deposition of Thomas O. Rouse taken pursuant to notice of agreement taken primarily pursuant to a 30(b)(6) notice of General Electric, and I understand that Mr. Rouse will be testifying on behalf of the General Electric on various topics in this case. The 30(b)(6) notice to General Electric, specifically those topics relating to contamination of mineral oil dielectric fluids with PCBs, and, in addition, the formation of PCDFs or PCDDs as a result of arcing in transformers. Is that the basic topic that he's going to be talking about?

MR. COCHRAN: Yes. You comfortable with that?

THE WITNESS: Yes.

* * * *

[28]

Q Is PCB, in any of its congeners, an appropriate additive to mineral oil?

A Not that I know of.

Q Does it belong in mineral oil, dielectric fluids?

A It is not intended to be in any. General Electric uses, as a matter of fact, in the ASTM and in your local internal GE specifications there is a maximum of two parts per million PCB allowed. So, in a sense, the specification says there shouldn't be any measurable amount of PCB in the mineral oil.

Q We had a confusing discussion yesterday in the lower [29] limits of detection.

A The lower limits. What I'm talking about here are for method D-4059, which is also an AA method.

Q What that means is if there was one part per million, it would — no, if there was three parts per million, it would show three parts per million by that testing?

A That's a somewhat simplified but correct view of it.

Q Simplified but correct is the best I can hope for.

A I'd probably describe it much the same myself.

MR. COCHRAN: You can put "PPM" for parts per million.

A Or, if you would like, micrograms per gram.

Q Does PCB in mineral oil serve any beneficial purpose?

A PCB in mineral oil?

Q Yes, sir.

A Not that I'm aware of.

* * * *

[33]

Q Do PCDDs have any place in mineral oil transformers?

A They should not. I am not aware of any finding that suggests PCDDs are formed by the chlorination of any of the hydrocarbons in transformer oil.

Q How about PCDFs?

A I am not aware of anything that should involve the chlorination of the hydrocarbons in mineral oil for PCDFs. On chemical grounds, I would think it even less likely.

Q With respect to PCDFs and PCDDs, do they serve any useful purpose when contained in a dielectric fluid?

A I'm not aware of any.

Q Do they incr[illegible] the risk of harm to human health?

A I cannot answer that. That's not my area of expertise.

* * * *

[37]

Q But was there a need for the test whether it's done in the field or otherwise because General Electric was becoming aware that around one in every four mineral oil transformers had some level of PCBs in [38] them?

A The initiative for this program, as I recall it, came from the EPRI.

Q Did EPRI have some understanding that around one in every four transformers had some level of PCBs in them?

A I do not know.

MR. COCHRAN: Object to the form.

Q Do you know what level, what percentage of mineral oil transformers could be expected to have some level of PCB contamination?

A It has been estimated, in approximately 1988 or '89, that there was some 35 odd mineral oil containing — 35,000,000 odd mineral oil containing transformers in service in the U.S. My recollection of that same study indicated that there was some 2,000,000 thought perhaps to contain measurable quantities of PCBs and some 200,000 of those to contain in excess of 500 parts per million PCBs.

Q Would it surprise you, on a given utility, when they were running their test of dielectric fluids that they were finding between a fifth and a quarter of all of the transformers had some measurable level PCBs in them?

[39]

MR. COCHRAN: Object to the form. The question assumes facts that are not and will not be in evidence in this case, but go ahead.

A I am [neither] surprised nor nonsurprised by that.

Q Well, the numbers that you just gave me, if my math is right, would be about one in every 16 transformers roughly. Does that sound like the percentage you gave me?

A Something like that. I believe your math is correct.

* * * *

[49]

MR. WARSHAUER: Appendix A which is dated "Estimate 1988 PCBs Equipment Inventory File Report".

BY MR. WARSHAUER:

Q So, instead of the rough estimate we talked about earlier, 1 in 16, it's closer to 1 in 10?

A That's their estimate, yes.

Q And you think that sounds like a fair estimate?

A I'm sure they knew what they were doing in 1988. As I indicated a minute ago, I suspect that as older transformers are replaced in service, the number of transformers that contain traces of PCBs has gone down since replacement. New transformers do not have PCBs in them. I would think the numbers are somewhat lower today.

Q And the last date of potential contamination would have been 1977 when the industry stopped making PCB askarel transformers?

A Yes, and the regulation controlling the manufacturer [50] went into effect in '78. I'm sure there was action before that by the manufacturer.

Q When you checked back 10 years earlier than 1988, just as you expected, a decrease would exist in 1990. Would you find a slightly higher percentage in 1988?

A That's correct, and that report that we were just entering into the discussion, discussed a similar study that was done back in about 1980. And you're right, that's exactly what they concluded.

* * * *

[61]

Q Let's talk about the first one, oil's contamination. You mentioned to me that you all were not finding PCB levels in oil that arrived to the factory, so is this oil contamination taking place during the manufacturing process?

A We have found PCBs in the oil in our plant lines. The analysis that we performed that indicated that took place starting in about 1968.

Q Do you believe that your first contamination of mineral oil was 1968 or that's the earliest test that [62] you have where you —

A That is the earliest test that we have to indicate that.

* * * *

[67] Transformers are filled and drained for various purposes. A transformer could be inadvertently filled with askarel and drained into an oil line; equally so, a transformer could be inadvertently drained with oil and drained into the Pyranol line. There is no intention to do this sort of thing because Pyranol is considered, I believe, more expensive than oil, so it's a relatively precious commodity. Oil defeats the nonflammability aspect, character, of Pyranol, and Pyranol defeats the economics of use of oil; oil means that you're adding a higher cost fluid to a lower cost fluid to no purpose. So, in all cases, these kinds of actions of mixing were unintentional.

Q They were mistakes?

A What?

Q Were they mistakes?

A I think you could characterize them as mistakes.

* * * *

[69]

Q From 1935 — was that about the first date that General Electric first started putting PCBs in their askarel transformer?

A The records indicate 1934, 1935.

Q From that date until 1960, would it be fair to say distribution transformers that might have been contaminated with Pyranol PCBs would have been [70] manufactured at the Pittsfield facility?

A Yes, that's correct. There was a manufacturing plant for distribution transformers in Oakland, California from, I'm not exactly sure when it began; I would think in the '50s, and it was closed about 1973 and it was intended for supply of transformers to the far western part of the United States.

Q But did it use PCBs?

A It used both.

DEPOSITION OF DR. JOHN F. BROWN, JR.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

EXAMINATION BEFORE TRIAL of the DEFENDANT, GENERAL ELECTRIC COMPANY, through and expert witness, DR. JOHN BROWN, conducted pursuant to the Federal Rules of Civil Procedure, before Lillian M. Cunniff, a Shorthand Reporter and Notary Public in and for the State of New York, held at the Desmond Americana, Albany-Shaker Road, Albany, New York, on Monday, July 26, 1993, commencing at approximately 12:30 p.m.

* * * *

[6]
DR. JOHN F. BROWN, JR., called by the plaintiff, having first been duly sworn by the Notary Public, was examined and testified as follows:

* * * *

[7]
Q What is your present occupation?
A My present occupation is Manager of Health Research at the named organization, General Electric Corporate Research and Development.

* * * *

[11]
Q By the mid 1980's, were you aware of any particular risk to human health associated with PCDD's or PCDF's?
A We had been following — I had been following the literature on alleged human health hazards since 1975

* * * *

[48]
Q Would you agree with me that it is foreseeable that in such instances PCDF's will exist at some level in PCB products, such as Aroclors?

* * * *

A I think I already testified that PCDF's can be found in electrical grade PCB's, at levels of from zero to two parts per million in what we have seen, and that these levels are toxicologically insignificant.

* * * *

[57]
Q It's your opinion that the dioxin group is a promoter, not an initiator?
A Yes. And again, it can serve as either a promoter or an inhibitor, depending on the animal test system.
Q Do you have an opinion as to its effectiveness as a promoter? Does it do a good job, or does it hardly promote at all?
A Dioxin is a material which has its pharmacological effect at very low levels; that is, it's a very potent agent either as a promoter or as an inhibitor.

* * * *

[61]
Q But you would agree PCDF's and PCDD's don't belong in either Pyranol or Aroclor?
A I think they were not intentional constituents, but they have always been there.

[97]

Q Are you familiar with the work of Arnold Schecter on the subject of PCB's?

A Arnold Schecter has written a hundred papers on PCB's and dioxins, mostly dioxins. I have not read them all.

Q Do you consider him to be authoritative; his papers?

A Just the papers?

Q The ones you have read, did you find them to be consistent with scientific knowledge and authoritative with something published in your line? [98]

A Where he has reported data on observed environmental levels, the results are as good as the laboratories doing the work. I have known Arnold Schecter for quite awhile. I'm rather skeptical of his interpretations, as are many other people, and I would not regard his interpretations of the analytical data he has gathered as scientifically authoritative.

EXHIBIT 3 TO SUMMARY JUDGMENT OPPOSITION

WESTINGHOUSE ELECTRIC
AND MANUFACTURING COMPANY
SHARON WORKS

Process Specification
No. SH-290504-A

April 12, 1945

PREPARATION OF TRANSFORMERS
AND COMPARTMENTS FOR SHIPMENT

GENERAL:

This specification covers the precautionary measures to be taken during the assembly and testing of transformers and compartments, to have assurance that the internal parts are free of contaminating material previous to shipment. Compartments may or may not be attached to transformers.

NOTE: This specification is a revision of Proc. Spec. No. 290504-A, dated March 18, 1938, issued at East Pittsburgh and is now being issued as a Sharon specification with the sub letter A.

CAUTION: DO NOT BREATHE VAPORS FROM INERTEEN. AVOID CONTACT OF IT WITH THE SKIN. WORKMEN SHOULD NOT ENTER A TANK WHICH HAS CONTAINED INERTEEN UNLESS THEY ARE WEARING PROPER RESPIRATORS, OR UNLESS THE TANK IS PROPERLY VENTILATED

* * * *

EXHIBIT 4 TO SUMMARY JUDGMENT OPPOSITION

Headquarters Medical Dept.
September 15, 1947

CLEVELAND WORKS
Mr. J.W. Wigert
Materials & Process Engr.

I am sorry for the long delay in getting the Safe Practice Data Sheet I-1 prepared. We are still lacking some data on inerteen, but rather than waiting until we get complete information I will send you the following, which takes care of most of the data. I discussed your capacitor installation with several persons at your plant sometime ago, including Mr. T.E. Fuller and Mr. J. Scott. They are familiar with the fact that inerteen is a fairly toxic material which must be handled in such a way as to prevent poisoning.

CONTAINERS AND STORAGE

I believe the type of container is indicated on P.D. Spec. 6935. You can probably determine the exact type of contained in which you receive this material from your supplier. There are no special precautions that need be taken in storing the original containers. In case of spillage, the inerteen should be cleaned up promptly so that its vapors will not contaminate the storage area. The use of oil absorbing compound, M#8695-1, is recommended since this compound absorbs the inerteen and keeps the floor in a non-slippery condition.

PROPERTIES

Fire — Non-flammable

Explosion — Non-explosive

BREATHING

I do not yet have data on the odor level of this material. Chronic poisoning may occur where there are repeated exposures or recurring exposures to a sufficient concentration of inerteen (6935) vapor over a period of months or years. Such exposures may produce internal bodily injury which may be disabling or could be fatal. Where people may breath air containing the vapor, the Maximum Allowable Concentration is one milligram per cubic meter. This Maximum Allowable Concentration applies to repeated or recurring daily exposures. If the concentration is less than one milligram, there is little chance of poisoning even after years of exposure. When much higher concentrations of vapor are breathed for a relatively short period, there may be irritations of the nose and throat, or, occasionally nausea. If air is saturated with inerteen vapor at room temperature, it will contain a concentration of .176 milligrams of inerteen per cubic meter of air. (Note) I am not entirely satisfied with this figure, although it is the best data that I have available. I expect to check this value before issuing the Safe Practice Data Sheet. Even though this relatively high concentration of vapor could be theoretically produced at room temperature, it must be remembered that its evaporation rate at room temperature is very slow and it would require long periods of time, in a totally enclosed space, to reach this saturated condition.

SWALLOWING

Inerteen is highly toxic if taken internally. The swallowing of approximately one or two ounces may cause serious internal injury or perhaps death.

SKIN IRRITATION

It is a mild skin irritant. Even though it is not very irritating to the skin, it is absorbed through the skin and can produce toxic reactions internally. It may also produce, after exposures of months or years, a skin condition known as chlor-acne. This condition is very difficult to heal.

PERSONAL PROTECTIVE EQUIPMENT

If it is necessary, under emergency conditions, to enter a space containing very high concentrations of vapor or fume, either a universal gas mask, M#6759-1, an air-line respirator, or a hose mask with or without blower, may be used. For usual concentrations of vapor, standard chemical cartridge respirator 8883-1, equipped with an activated charcoal cartridge 8883-2, will provide protection. These respirators should be of a type approved by the U.S. Bureau of Mines. Neoprene aprons and gloves 7530-6 may be used where necessary to protect the skin. If for any reason the neoprene gloves do not stand up well on this application, a glove made from Polyvinyl alcohol resin (such as Resistoflex) could be used. Hand cream, such as West 88 (West Disinfectant Company, 42-16 West Street, Long Island City), or Fend C (Mine Safety Appliances Company, Pittsburgh, Pa.) may be of some value as protection for the skin where better methods of protection are not practical.

PRECAUTIONS

Care must be taken to prevent any appreciable contact of this material with the skin, especially when these contacts are repeated. If any appreciable area of the skin becomes coated with the inerteen, it should be removed by washing with soap and water. Butyl stearate is a good solvent for this material and can be used to aid in completely removing the inerteen from the skin. Its use should always be followed by washing with soap and water. The Maximum Allowable Concentration of vapor, previously specified, should not be exceeded under normal working conditions. This can be accomplished either by using a totally enclosed system or by providing adequate ventilation. Where this is not practical, respirators may be used. Proper preplacement and periodic physical examinations should be made by the Medical Department on workers who work with inerteen.

FIRST AID

In cases of swallowing, vomiting should be induced immediately by carefully inserting a finger in the person's throat. In case of any severe exposure, the person should be placed under the supervision of the plant physician.

E.C. Barnes
Industrial Hygiene Engineer

ECB:y

EXHIBIT 8 TO SUMMARY JUDGMENT OPPOSITION

THE EPPLEY INSTITUTE
for
RESEARCH IN CANCER

November 19, 1975

Frederick R. Johannsen, Ph.D.
Toxicologist
Monsanto Company
800 N. Lindberg Blvd.
St. Louis, Missouri 63166

Dear Dr. Johannsen:

With regard to my letter of October 17, 1975 and our telephone conference concerning your data, I am happy to report that analyses are now complete. I would, however, first like to comment briefly on the methods of analysis employed and the possible conclusions.

When the data is analyzed from the life table approach, one concludes that mortality rates from all causes of death among this group of employees are not materially different from those which are expected on the basis of the national mortality experience. Indeed, this mortality is lower, on the average, than the national mortality.

The mortality due to lung cancer, however, ranges from between three- and ten-fold, when compared to the figure expected, and the increased rate is significant.

The third category of analysis was done from the perspective of the age at which employees were initially exposed. The deaths due to all causes show no discernible relationship between mortality and the age at which employees were exposed (see computer output tables). In the case of persons who died of lung cancer, the time intervals between initial exposure to the K Plant

and death are as follows: 9, 9, 17, 17, 19 and 26 years. Their ages at the time of hiring were 31, 33, 38, 42, 42 and 50 years and their ages when first exposed were 39, 43, 45, 45, 47 and 50 years (see the attached table). Furthermore, all six of the lung cancer victims worked for less than 3 years in the K Plant, and 3 of them worked for less than three and one half months. Therefore, it would be useful to look into their occupational backgrounds prior to their hiring by Monsanto. The absence of other information, especially with regard to their smoking habits, and the fact that the total number of employees in question (after considering those lost in terms of follow-up) is too small, make it difficult to attribute these lung cancer cases to the employment at K Plant.

It has been common practice in United States hospitals for the last 15 years to collect information on the extent and duration of the smoking habits of each lung cancer victim, and thus the smoking histories of the six cases under scrutiny should be obtainable from the corresponding hospital records. One may be able to judge the situation more clearly if this information were obtained and made available.

The results of this study do not indicate dose-response relationships, either for all causes of death or for lung cancer.

For your use, I will send all the computer output tables under separate cover. I will retain the information sheet you sent and the coding forms, unless you wish to have them returned.

Please do not hesitate to call me for additional consultation.

Sincerely,

/s/
E. Mahboubi, M.D.
Professor and Head Epidemiology

ah

* * * *

EXHIBIT 9 TO SUMMARY JUDGMENT OPPOSITION

Monsanto
From (Name & Location) Dept. Of [M]edicine & Environmental Health - F.R. Johannsen, A2SC

Date: August 27, 1976
Subject: Epidemiology
Reference: Krummerich Plant
To: G. Roush
A2SA

A group of 311 present/former W.G. Krummrich Plant employees have been compiled. Each of the 311 is known to have worked in Dept. 246, based on work history records. Information on the cause of death has been obtained on 50 former employees from this group. Evaluation of death certificates attribute 6 of those deaths to lung cancer.

A review of this population, omitting all those who worked in Dept. 246 for less than 6 months, yielded the following sub-population:

total number of employees	- 140
identified deaths (all cases)	- 23
deaths attributed to lung cancer	- 4

When compared to the 1969 U.S. male population, this group of 23 deaths would be expected to contain 1.24 cases attributable to lung cancer. Statistical comparison of the observed lung cancer versus the expected lung cancer yielded a highly significant chi X^2 value of 7.1. This number is even more significant than the value (chi $X^2 = 6.8$) obtained following evaluation of the full 50-person mortality population.

/ s /
Frederick R. Johannsen

alw

EXHIBIT 11 TO SUMMARY JUDGMENT OPPOSITION

Mortality of PCB Workers at
the Monsanto Plant in Sauget, Illinois

Judith A. Zack and David C. Musch

December 14, 1979

* * * *

[3]

The literature on PCB toxicity points to several organ sites in man that could potentially incur toxic effects of exposure to PCBs. The present study represents a completed analysis of the preliminary study of Monsanto PCB workers reported in 1976.

* * * *

[4]

Results

Eighty-eight of the eighty-nine members of the study cohort were traced. Fifty-eight were verified living and thirty were verified deceased by death certificate. The results of this vital status tracing are shown in Table 1.

The person-years of observation contributed by the eighty-nine member study cohort are shown in Table 2. A total of 1800.1 person-years were observed at all ages. Most of these person-years were observed in the middle-age range with 1333.1 person years (74%) observed for ages 35-60.

Table 3 categorizes duration of exposure to PCBs by vital status. For both living and deceased workers, the majority were exposed less than three years. The next frequent exposure class was for five or more years of exposure. The least number of workers fell in the three to five years of exposure category.

Overall, the average length of exposure for living and deceased workers was similar with deceased workers having 3.7 years of exposure and living workers having slightly less at 3.2 years.

The mortality experience for all males is summarized in Table 4. The mortality of white and nonwhite males is examined separately in Tables 5 and 6. Observed and expected deaths and SMR's are shown for each of the nineteen cause-of-death categories examined.

[5]

For all males, there were 30 deaths observe and 22.88 expected (Table 4). The overall SMR was 131. For malignant neoplasms, 8 deaths were observed with 4.46 expected. The SMR for all malignant neoplasm[s] was 179. No deaths were observed from liver or pancreatic cancer or from malignant melanoma. The SMR for lung cancer was high at 278. The only statistically significant difference seen in this table is seen for diseases of the circulatory system, exclusive of arteriosclerotic heart disease. Nine deaths were observed with 3.98 expected, yielding a SMR of 226.

Table 5 shows the overall SMR remains high for white males at 133. There were 4 deaths from cancer with 2.70 expected. None were from liver or pancreatic cancer or from malignant melanoma. The high SMR's seen in Table 4 for lung cancer and the residual diseases of the circulatory system appear to be explained by the high SMR's for these causes in white males. There were 3 deaths observed from lung cancer with 0.94 expected, yielding a SMR of 319. For the category of circulatory disease, exclusive of arteriosclerotic heart disease, the SMR was 526 with 7 observed and 1.83 expected deaths. This difference was the only one of statistical significance in this table.

For nonwhite males, there were no statistically significant differences seen in Table 6. The overall SMR was also high at 128. Four deaths from cancer were observed with 1.76 expected, but none from liver or pancreatic cancer or from malignant melanoma.

Case histories for the eight cancer deaths are summarized in Table 7.

No. 96-188

Supreme Court, U.S.
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IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,
v.
ROBERT K. JOINER, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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IN THE
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Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Eleventh Circuit

REPLY BRIEF FOR PETITIONERS

Respondent's brief shows a major reluctance to face the issue on which this Court granted certiorari: the standard of appellate review. Nearly all of petitioners' opening brief remains unanswered or conceded. Respondent scarcely attempts to defend the "particularly stringent" standard of review the Court of Appeals adopted. P.C.A. 4a.[1] In fact, respondent appears to acknowledge that the correct standard, as nearly all federal circuits and state courts have held, is one of "abuse of discretion" or "manifest error." See Resp. Br. 26.

I.

It takes many pages before respondent acknowledges the issue before this Court: what was the correct standard of appellate review to apply to the District Court's decision? Respondent's entire effort to defend the Court of Appeals' one-way "particularly stringent" standard of appellate review—applicable only when expert opinion is

[1] "P.C.A." refers to the appendix to the petition for certiorari, and "S.A." to the appendix to respondent's brief; other references are as noted at Pet. Br. 1 n.1.

excluded under Rule 702 and summary judgment results —is confined to one long footnote. Resp. Br. 30 n.48. "There are two possible grounds," respondent says, "for devoting greater appellate resources to reviewing the exclusion of critical evidence than its admission." *Id.* First, he argues, Federal Rule of Evidence 702 creates an "explicit statutory presumption in favor of admitting relevant evidence" that "[p]resumably . . . justifies devoting at least *some* additional appellate resources." *Id.* (emphasis in original). Second, he says, exclusion "can impair the full realization of a significant constitutional value —the Seventh Amendment guarantee of a jury trial." *Id.*

For his footnoted Rule 702 argument, respondent cites only a general reference to the "liberal thrust" of the Federal Rules of Evidence and their "relaxing the traditional barriers to 'opinion' testimony" in *Beech Aircraft Corp.* v. *Rainey*, 488 U.S. 153, 169 (1988), and the Court of Appeals' belief that liberalization of evidentiary procedure means a "preference for admissibility." Resp. Br. 30 n.48, quoting P.C.A. 4a. But as *Daubert* made clear, "relaxing the traditional barriers"—such as the traditional requirement that experts testify in the form of responses to hypothetical questions, or the traditional ban on expert testimony as to the ultimate issue—does not mean allowing opinions that are found to lack scientific support. Quite the contrary. See *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589-90 (1993). The policy of Rule 702 is already incorporated in the *Daubert* standard that district courts apply. The Rule provides no additional basis at the appellate level to reverse district courts that exclude unsupported opinions under *Daubert*. Respondent confuses the selection of the proper standard of appellate review with the subsequent and distinct issue whether, after applying a proper standard of review, any error identified requires reversal. See Fed. R. Evid. 103(a).

For his footnoted Seventh Amendment argument, respondent cites an opinion saying that "a more searching inquiry" should be given to grants of new trial that overturn jury verdicts for insufficient evidence. *Langevine* v. *District of Columbia*, 106 F.3d 1018, 1023 (D.C. Cir. 1997). But certainly *Daubert* settled that the trial court's traditional role of determining admissibility, which Federal Rules of Evidence 104(a) and 702 reflect and reinforce, does not implicate the Seventh Amendment. See 509 U.S. at 597; *cf.* also, *e.g.*, *Markman* v. *Westview Instruments, Inc.*, 116 S. Ct. 1384, 1393-95 (1996); *Galloway* v. *United States*, 319 U.S. 372, 390 (1943) (in 1791 "as now courts excluded evidence for irrelevancy and relevant proof for other reasons").

II.

Instead of even attempting to confront the mountain of authority against a one-way "particularly stringent" standard of review, see Pet. Br. 19-45, respondent searches (as he did in opposing certiorari) for some way to escape the issue in this case. He first tries to dismiss the Court of Appeals' "particularly stringent" standard as nothing more than a comment on "efficient allocation of judicial resources." Resp. Br. 28 n.45. Alternatively, respondent says that review by this Court is not called for because, as he reads it, the Court of Appeals' review standard really was *de novo*, and its explicit adoption of the "particularly stringent review" standard was all a dictum it never applied. Resp. Br. 19, 31, 34. Neither attempt at evasion works.

1. Respondent says that the Court of Appeals' adoption of the "particularly stringent review" standard amounted "simply" to an observation about selecting the issues to which "appellate courts will devote more time and attention." Resp. Br. 27. All that is meant by "par-

---

[2] For this anodyne explanation respondent quotes repeatedly the *Paoli* opinion's phrase "hard look." But that was not the term used by the Court of Appeals here, which held that "we apply a *particularly stringent* standard of review." P.C.A. 4a (emphasis supplied), citing *Paoli*. And *Paoli* itself explained that what it meant by "hard look" was "more stringent review." 35 F.3d 717, 749-50.

ticularly stringent" review, he says, is "reserving extra judicial time and attention for important admissibility decisions, and less time for trivial ones." Resp. Br. 29.[3] He does not explain how a ruling on the same admissibility objection can at once be "trivial" if a district court decides to admit, but "important" if the court decides to exclude.

No one else has ever thought the issue was merely one of "judicial resources."[3] The *Paoli* court, which invented the "particularly stringent" standard, explained that its standard of appellate review was designed to make exclusions under Rule 702 more likely to be reversed on appeal than if the opinions had been admitted:

> *"the likelihood of finding an abuse of discretion is affected* by the importance of the district court's decision to the outcome of the case."

In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 750 (3d Cir. 1994) (emphasis supplied), *cert. denied sub nom. General Elec. Co.* v. *Ingram*, 115 S. Ct. 1253 (1995).[4] And other courts of appeals have recognized *Paoli* and the present case as creating a significant split of authority. See *Duffee* v. *Murray Ohio Mfg. Co.*, 91 F.3d 1410, 1411 (10th Cir. 1996) (rejecting "particularly stringent" standard). They have noted their anticipation that this Court will resolve this "disagreement among the circuits" in this case. *Cortes-Irizarry* v. *Corporacion Insular de Seguros*, 111 F.3d 184, 189 n.4 (1st Cir. 1997).

2. Respondent seeks to elude this Court's review by arguing that actually the Court of Appeals did not really

[3] Justice Holmes' "concession to the shortness of life" that respondent cites had nothing to do with appellate review, but rather explained why collateral evidence is not admitted in trials. See Resp. Br. 28 n.45, quoting *Reeve* v. *Dennett*, 145 Mass. 23, 28, 11 N.E. 938, 944 (1887).

[4] In *Paoli* itself the court of appeals, using its newly-minted "more stringent" standard, reversed a District Court's exclusion of opinions of several scientists even though the district court had held a five-day evidentiary inquiry into their methodology or lack thereof. See 35 F.3d at 766, 767, 771, 772.

apply the *Paoli* "particularly stringent" standard it explicitly adopted. Instead, he argues that the Court of Appeals applied an even less deferential standard—*de novo* or plenary review—and that "the district court's rulings all were reversed for errors of law." Resp. Br. 19; see also *id.* at 20, 31.

(a) Respondent forgets that even if his characterization of the Court of Appeals' standard as *de novo* or plenary review were accurate, that still would not alter the question before this Court, which is:

> "What is the standard of appellate review for trial court decisions excluding expert testimony under *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)?"

Pet. Cert. i. That question "fairly include[s]," Sup. Ct. Rule 14.1(a)—indeed, expressly includes—determining the correctness of *whatever* standards of appellate review the Court of Appeals applied. See, *e.g.*, *Yee* v. *City of Escondido*, 503 U.S. 519, 535 (1992).

(b) The Court of Appeals nowhere disagreed with the District Court's explication of Rule 702 and *Daubert*. The District Court explained that under Rule 702 "the basic methodology employed to reach . . . a conclusion [must be] sound." P.C.A. 67a, quoting *Wells* v. *Ortho Pharmaceutical Corp.*, 788 F.2d 741, 745 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986). The Court of Appeals agreed that the trial judge must "make a 'preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid.'" P.C.A. 6a, quoting *Daubert*, 509 U.S. at 592-93. The Court of Appeals' disagreement was with the District Court's performance of the "gatekeeping" function; it held the District Court had "improperly assessed" the particular opinions' admissibility. P.C.A. 2a.

Respondent stresses one comment in the District Court's lengthy opinion, that petitioners were successfully "attacking the conclusions that Plaintiffs' experts *draw from the studies they cite*." P.C.A. 58a (emphasis supplied). The District Court was simply pointing out the fundamental

methodological flaw that petitioners were highlighting: that the opinions could not by scientific reasoning and logic be "draw[n] from the studies they cite." The Court of Appeals similarly faulted the District Court for referring to lack of support for particular conclusions rather than "viewing the bases of an expert's opinion as a whole." P.C.A. 13a. But if a district court, in determining whether an opinion rests on scientific methodology, oversteps its "gatekeeping" function,[6] that would be an abuse of discretion, not an error of law.

Respondent observes that "District courts do not have 'discretion' to misinterpret the Federal Rules of Evidence." Resp. Br. 20. Indeed they do not. And neither do courts of appeals, by obliterating the discretion assigned to trial judges by Rules 104(a) and 702. Under respondent's proposed deconstruction of the Court of Appeals' ruling, virtually any case in which a district court excluded expert testimony under Rule 702 for failure to provide scientific support for the opinions could be recharacterized as a misconstruction of Rule 702. Asserted error in a discretionary ruling would be transmuted into error of law, to be revised completely on appeal *de novo*. Appellate judges, rather than trial judges, would become the first-line Rule 702 "gatekeepers."

(c) Respondent by calling this *de novo* or plenary review really is condemning what occurred. The "particularly stringent review" the Court of Appeals exercised indeed was so devoid of any deference to the trial judge that it did amount virtually to reexamining the record *de novo*—not based on the District Court's use of an incorrect legal standard, but rather because the Court of Appeals took over the "gatekeeping" role. Obviously

[6] That did not occur here. The District Court plainly was referring to an absence of methodology, that the premises offered no support for the conclusions. It was not saying, for example, that it simply disagreed with or would not accept a conclusion that PCBs could cause human small-cell lung cancer, or that without regard to methodology it preferred the opinions of one set of experts over those of another.

such a standard applied to the District Court's "gatekeeping" judgment would be even more difficult to justify under Rules 104(a) and 702 than the "particularly stringent" review the Court of Appeals described.

III.

Respondent opens his brief with a lengthy excoriation of PCBs. He says that "PCBs have long been regarded as extremely hazardous to humans." Resp. Br. 1. He quotes an opinion of this Court summarizing a bankruptcy record that referred to PCBs as "highly toxic carcinogen[s]." *Id.*, quoting *Midlantic Nat'l Bank* v. *New Jersey Dep't of Environmental Protection*, 474 U.S. 494, 497 (1986). He cites a law enacted in the 1970s that prohibited production of PCBs. Resp. Br. 1 n.2, citing Toxic Substances Control Act, § 6, 90 Stat. 2003, 2020 (1976), as amended, 15 U.S.C. § 2605. He also cites occasional characterizations of PCBs by the Environmental Protection Agency and other administrative agencies that assume the human carcinogenicity of PCBs. Respondent misconceives the relevance of such materials. Neither dicta in court opinions nor statements from administrative agencies constitute scientific evidence admissible in court, or add a particle to what science does or does not know.

1. Respondent makes much of EPA's inclusion of PCBs in its category of "probable human carcinogens." Resp. Br. 1-2. But regulatory bodies, quite properly, characterize substances and evaluate their risks for very different purposes than determining scientific proof of legal causation. See generally S. BREYER, BREAKING THE VICIOUS CIRCLE 47-50 (1993). As a policymaking body, EPA is free to base its actions on evidence and reasoning too unreliable to be "[s]cientific knowledge" admissible in court. "[S]peculation, conflicts in evidence, and theoretical extrapolation typify [regulators'] every action." *Ethyl Corp.* v. *EPA*, 541 F.2d 1, 24 (D.C. Cir.) (*en banc*), *cert. denied*, 426 U.S. 941 (1976). But speculation by a scientist in court is inadmissible under Rule 702. See, *e.g.*, *Diviero* v. *Uniroyal Goodrich Tire Co.*, 114 F.3d

851, 853 (9th Cir. 1997). The policy criteria EPA uses to evaluate carcinogenicity for regulatory purposes[6] are not the scientifically reliable methodology required to form an opinion about the cause of human disease under the Federal Rules of Evidence in a tort case. Nor do they purport to be. As the Fifth Circuit has explained:

> "Regulatory and advisory bodies such as IARC, OSHA and EPA utilize a 'weight of the evidence' method to assess the carcinogenicity of various substances in human beings and suggest or make prophylactic rules governing human exposure. This methodology results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances. The agencies' threshold of proof is reasonably lower than that appropriate in tort law, which traditionally makes more particularized inquiries into cause and effect and requires a plaintiff to prove that it is more likely than not that another individual has caused him or her harm."

Allen v. *Pennsylvania Engineering Corp.*, 102 F.3d 194, 198 (5th Cir. 1996) (quotation marks omitted).

Nor does respondent explain what EPA's term of art "probable human carcinogen" really means. In labeling a substance a "probable human carcinogen," EPA declares a statement of policy, not a finding of scientific fact. For convenience, EPA calls a "probable human carcinogen" any substance for which there is "sufficient" evidence (itself a specially defined term) of carcinogenicity *in animals*. See EPA, *Guidelines for Carcinogen Risk Assessment*, 51 Fed. Reg. 33992, 34000 (1986). Carcinogenicity in animals is determined by tests in which laboratory animals are administered the substance at or near the maximum tolerated dose level over a long period. *Id.* at 33994-95; see also J.A. 268-71, 305-06; S. BREYER,

[6] See EPA, *Guidelines for Carcinogen Risk Assessment*, 51 Fed. Reg. 33992, 33994-96 (1986). The International Agency for Research on Cancer (IARC) has published similar criteria, although the IARC uses somewhat different terminology. See *id.* at 33996; J.A. 236-37.

supra, at 44-46. EPA for its regulatory purposes treats even benign tumors in test animals as evidence of probable human carcinogenicity. 51 Fed. Reg. at 33994, and its list of "probable human carcinogens" is long. When respondent tells this Court that EPA classifies PCBs as a "group B2" "probable" human carcinogen, Resp. Br. 2 n.3, he ought to explain that the agency reserves that status for substances as to which there is *inadequate evidence* or *no data* regarding the effect on human beings. 51 Fed. Reg. at 34000.

2. The purpose of respondent's unexamined invocation of regulatory terminology appears to be to make the unsupported opinions of Drs. Schecter and Teitelbaum appear conventional and obvious. But they are not. Thus respondent urges on this Court the supposed

> "fact that the scientific consensus is in *his* favor, given that federal health authorities believe that it is 'probable' that PCBs cause cancer in humans, including lung cancer."

Resp. Br. 39 (emphasis in original). But the undisputed record before the District Court remains that that is not the "scientific consensus" at all. In fact, for any substance as to which there is sufficient evidence of carcinogenicity in human beings, EPA drops the "probable" label and classifies the agent as a "human carcinogen"—a label EPA does not apply to PCBs. 51 Fed. Reg. at 34000. Thus EPA's regulatory classification actually highlights the absence of scientific evidence that PCBs can cause cancer in humans. See *Conde* v. *Velsicol Chem. Corp.*, 24 F.3d 809, 814 (6th Cir. 1994) (EPA classification of chemical as "probable human carcinogen" based on animal studies is "not probative of medical causation by its own terms").

3. It may also be noted that the position of the United States, of which the EPA is a subordinate agency, is not only that the Court of Appeals' ruling here as to standard of appellate review should be reversed, but that the judgment of the District Court was so plainly a proper application of Rule 702 that no remand for further proceedings

is necessary. See Brief for United States as Amicus Curiae at 26 (District Court made "precisely the inquiry not only authorized, but mandated, by *Daubert*"), 30 ("[i]ts decision therefore should not have been disturbed on appeal").[7]

IV.

Most of respondent's brief is devoted to arguing that the District Court's exclusion was incorrect. Respondent repeats what no one contests: that Rule 702's requirement of "scientific . . . knowledge" is a requirement for scientific methodology. Resp. Br. 21-24. That, indeed, is exactly the point.

1. Respondent argues that for the "gatekeeper" to require, as the District Court did here, that "the conclusion *itself* must be logically supported, without too wide an analytic gap between the conclusion and the underlying data," must mean that "[i]n other words, to be admissible, the district court must believe that the conclusion is correct." Resp. Br. 45 (emphasis in original; quotation marks omitted). But respondent's "[i]n other words" does not follow at all. Prescribed limitations on inferring conclusions from data *is* scientific methodology.

It was the total failure to adhere to such scientific methodology—or any methodology—that the District Court found defective in respondent's two experts' opinions. They referred to epidemiological data and animal tests. But respondent's experts never used any coherent method to explain how the epidemiological data available could support a conclusion of causation with respect to PCBs and human small-cell lung cancer.[8] Respondent's experts

[7] Petitioners did not ask this Court to examine the record to determine itself whether the District Court abused its discretion. See Pet. Cert. 14 n.4. Whether remand for review of the record under the proper standard, or outright reversal, is the more appropriate disposition, this Court has ample discretion to decide.

[8] In epidemiology, for example, a fundamental methodological constraint dictates when an inference of causation is justified. Most often applied are Hill's Criteria, which list eight characteristics data must have "to make a reasonable inference of causation": strength of association; consistency of association; specificity of data; temporality; plausibility; coherence; experiment; and analogy. See NATIONAL RESEARCH COUNCIL, ENVIRONMENTAL EPIDEMIOLOGY 4 (1991); FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 160-66 (1994); K. FOSTER, D. BERNSTEIN & P. HUBER, PHANTOM RISK: SCIENTIFIC INFERENCE AND THE LAW 8-9 (1993). Neither Hill's nor any other discernible criteria were followed by respondent's two experts here.

also noted the existence of a few studies concluding that massive doses of PCBs could cause tumors (not lung cancer) in animals, and then leaped to conclude (without even knowing the dosage he had received) that PCBs can cause human cancer and had caused or promoted small-cell lung cancer in respondent. No scientific methodology informed those conclusions. The dissent called it "blue smoke and sleight of hand." P.C.A. 22a.

For district judges to require logical support without an analytic gap between data and conclusions is exactly what this Court in *Daubert* held Rule 702 commands:

> "The study of the phases of the moon, for example, may provide valid scientific 'knowledge' about whether a certain night was dark, and if darkness is a fact in issue, the knowledge will assist the trier of fact. However, (*absent creditable grounds supporting such a link*), evidence that the moon was full on a certain night will not assist the trier of fact in determining whether an individual was unusually likely to have behaved irrationally on that night."

509 U.S. at 591 (emphasis supplied). The District Court's holding was that "the basic methodology employed to reach . . . a conclusion [must be] sound," P.C.A. 67a, quoting *Wells, supra,* and that "the opinions of Plaintiffs' experts do not rise above 'subjective belief or unsupported speculation,'" P.C.A. 67a, quoting *Daubert,* 509 U.S. at 590. "The analytical gap between the evidence presented and the inferences to be drawn . . . is too wide." P.C.A. 67a, quoting *Turpin* v. *Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir.), *cert. denied*, 506 U.S. 826 (1992). As this Court explained in *Daubert,*

"in order to qualify as 'scientific knowledge,' an *inference* or assertion *must be derived* by the *scientific method*. Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known."

509 U.S. at 590 (emphasis supplied).

2. Respondent incorrectly tells this Court that "petitioners' experts had not offered any criticism of the methodology used by Teitelbaum and Schecter." Resp. Br. 13; see also Resp. Br. 9-11.[9] But abundantly they had:

(a) With respect to respondent's two experts' reliance on animal studies, petitioners' experts testified:

— "Experimental animals cannot predict; they only give us some clues and the suggestion of ways to go in humans." J.A. 276.

— "[T]he information [from animal studies] cannot be blindly extrapolated to humans." J.A. 265.

— "[Y]ou really can't necessarily correlate animal research to human research until the human research has been done." J.A. 306.

— "[B]efore you can really draw any conclusions about humans, you have to have data on humans, obviously, because they're different." J.A. 306.

— "[U]ltimately, the epidemiological studies are those on which we must rely." J.A. 276.

(b) With respect to respondent's experts' references to epidemiological studies, petitioners' experts testified:

— Epidemiological studies are evaluated "in the context of a set of criteria for making interpretations." J.A. 237.

— "We have the Hill criteria which we have to use for epidemiological studies." J.A. 272.

— "[T]he epidemiology studies have no consistency and no specificity. They vary from one

[9] The Court of Appeals also mistakenly stated that both Dr. Schecter and Dr. Teitelbaum "asserted the general acceptance of the procedures they employed and defendants do not challenge these claims." P.C.A. 11a.

study to another, and they're—none of them are significant." J.A. 272.

— "Based on the epidemiology we have now and the track record we have and what exposures have been, there is no evidence that there would be a situation which there would be adverse health effects." J.A. 274.

(c) With respect to respondent's experts' offering their opinions without any regard to the dose to which respondent had been exposed, petitioners' experts testified:

—"[A]t this point, I think there's no evidence of any health risk as far as small cell cancer is concerned, you know, in this—this particular exposure." J.A. 320.

— "[W]e have not seen effects in people who probably had adipose tissue levels as high as a thousand parts per million." J.A. 378 (Dr. Brown).

— "Anything is toxic if the dose is high enough." J.A. 274.

— "Mr. Joiner has not received a toxicologically-significant dose of PCBs." J.A. 280.

(d) With respect to respondent's experts' broad assertions that the scientific literature contained information to support their opinions, petitioners' experts testified:

— "[T]here was not even any circumstantial evidence in the literature that it [small-cell lung cancer] might be related to PCB . . . ." J.A. 308.

— On whether inhalation of PCBs could affect the respiratory system, "I know of no documentation or literature that there is, you know, a human cause of this in the human literature." J.A. 305.

— On PCB causation of cancer, "I don't think there's any evidence to suggest that . . . in humans." J.A. 382.

— "I think he's [Dr. Schecter] exaggerating the information we have available." J.A. 279.

— "I would not regard his [Dr. Schecter's] interpretations of the analytical data he has as scientifically authoritative." J.A. 379.

In fact, respondent's own experts refuted the methodology on which their opinions depended:

— As to animal studies, Dr. Teitelbaum testified that "I don't think there's an analogy in animals that would be relevant." J.A. 170.

— As to whether any study showed PCBs caused small-cell lung cancer in human beings or any other species, Dr. Teitelbaum testified that "there is no such study." J.A. 169.

— As to dosage, Dr. Schecter testified that the animal studies had reported tumors "in a dose dependent fashion," J.A. 112, but that "I have no opinion" about what dose respondent actually had been exposed to or absorbed. J.A. 118.

— As to epidemiological studies, Dr. Teitelbaum testified that "I don't think that . . . any of them would be willing to say that they have evidence, convincing evidence, that PCBs cause any single kind of cancer." J.A. 161. (Nevertheless, he explained, "the simple fact that it did not reach statistical significance isn't enough to convince me the study is not right." J.A. 164.)

3. Respondent also argues that petitioners' experts

> "used the very same methodology as Teitelbaum—they *looked at the same sources* of information as Teitelbaum, and *engaged in inductive reasoning* to assess the likelihood that these substances had promoted Joiner's cancer—and differed with Teitelbaum only as to the conclusion they reached using this methodology."

Resp. Br. 9-10 (emphasis supplied). He repeats similar assertions of agreement with the methodology of Dr. Schecter. *Id.* at 11-12; see also *id.* at 37 n.54. Not so.

To create the impression that Dr. Schecter and Dr. Teitelbaum based their opinions on conventional scientific methodology, respondent recites that both conducted physical examinations (limited ones), and reviewed respondent's medical history and potential exposure. Resp. Br. 38-39.[10] But they did not explain how any information so obtained sustained any conclusions other than that he had smoked, had a family history of cancer, and now had small-cell lung cancer. The two doctors then, respondent says, "utilized numerous scientific studies and authorities." Resp. Br. 39, quoting P.C.A. 10a. But the two doctors themselves conceded that none of those studies concluded that PCBs could cause any kind of cancer in human beings, much less that PCBs here had caused or promoted small-cell lung cancer in this individual. See J.A. 158, 160, 169-70, 189.

True, petitioners' experts also consulted the available data and studies. But thereafter they most assuredly did not use the "same methodology." Unlike respondent's experts, they did not ignore what the data and studies said.[11] They did not swear to opinions and conclusions that no study could be found to support.

V.

In a number of instances respondent's characterizations are not faithful to the record:

1. Respondent tells this Court that "[o]ne of petitioners' experts acknowledged, with remarkable understatement, that 'there are credible scientists who hold the view that PCBs are an established human carcinogen.'" Resp.

---

[10] The doctor who met with respondent only in the attorneys' office was, as respondent correctly notes, Resp. Br. 9 n.18, Dr. Schecter, not Dr. Teitelbaum. See J.A. 103-04, 449. Each met respondent only once, and neither ever ordered tests or discussed the case with the physicians who had actually treated respondent. See J.A. 103-04, 138, 139, 403-04, 449-50.

[11] Dr. Schecter actually rejected the laboratory data of respondent's actual exposure—on the scarcely scientific ground that he did not choose to believe it. See J.A. 123-24, 129-30, 407. The uncontradicted record was that the laboratory tests had been properly performed. J.A. 383-85.

Br. 2 n.3, quoting J.A. 235. But what the cited testimony actually reads is:

> "A. The question is: Do I recognize that there are credible scientists who hold the view that PCBs are an established human carcinogen?
>
> "Q. Yes.
>
> "A. The answer is that *I cannot deny that there are such people, but I don't know who they are.*"

J.A. 235 (emphasis supplied). Elsewhere the same witness testified that there is no cancer in human beings "known to be caused or promoted by PCBs." J.A. 233.

2. Respondent at one point argues that to conduct epidemiological studies of PCBs would be impossible, because experimentation on human beings would not be lawful or ethical. Resp. Br. 40. He is confused. Studies using authorized ingestion of chemical substances by human beings, such as those testing new potentially beneficial drugs, are *experimental* or *clinical* studies, not *epidemiological*.[12] Epidemiological studies do not involve human experimentation; rather, they statistically analyze health effects in a population that has—independently of the study—been exposed to certain agents, to determine whether that population develops certain diseases at a higher rate than an unexposed population. See generally FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 129, 131-38 (1994).

Respondent's own experts made reference to several epidemiological studies that have been conducted of factory workers and others exposed to PCBs—and the record

[12] See CASARETT & DOULL'S TOXICOLOGY 951-54 (M. Amdur *et al.* 4th ed. 1991) (clinical studies involve experimentation with volunteers when there is little or no risk of damage or injury). When respondent says that petitioners' expert Dr. Waddell testified "that a controlled *epidemiological* study on humans would 'give them a dose' of PCBs 'to see whether they get lung cancer,' " and would be improper, Resp. Br. 40 n.55 (emphasis supplied), quoting in part S.A. 59, respondent confuses *epidemiological* with *clinical*. Dr. Waddell was not confused. See S.A. 59.

was undisputed that none has found a statistically significant correlation between such exposure and cancer. See J.A. 161, 163-64; P.C.A. 63a. When Dr. Teitelbaum said that it would be "impossible" to obtain epidemiological evidence that would satisfy him, he was complaining about sample sizes, not confusing epidemiological studies with clinical tests.[13] The hurdle facing respondent was not that there are no epidemiological studies looking for a link between PCBs and human cancer, or that such studies are impossible; rather, it was that no such study has found statistically significant evidence that such a link exists.

3. Respondent clouds the nature of Dr. Teitelbaum's career by delicately stating that Dr. Teitelbaum testifies "at only three or four *trials* a year, and in some years he does not appear *in court* at all." Resp. Br. at 8 n.17 (emphasis supplied). What respondent omits is that in an average year Dr. Teitelbaum also appears in depositions and administrative hearings. See J.A. 175-83. Asked how often he testifies during the nine months annually he is in this country, J.A. 167-68, Dr. Teitelbaum replied that "probably 30 to 40 times per year would be a reasonable guess." J.A. 166.

4. Respondent tells this Court that "petitioners now accept the view set forth in Joiner's opposition to certiorari (at 8-13) that *all* circuits apply an abuse-of-discretion standard, although some judges occasionally use older 'manifest error' language to express precisely the same level of deference to district courts." Resp. Br. 26 (emphasis in original), citing Pet. Br. 24-26. However, petitioners did not, by quoting respondent's concession that a deferential standard of review has been virtually universal, agree that all circuits currently so hold, because of course the Third and Eleventh do not.

[13] Certainly petitioners' experts did not, as respondent unaccountably says, "agree[]" with Dr. Teitelbaum's assertion that useful epidemiological studies were "impossible." Resp. Br. 40.

VI.

Finally, respondent now argues that the exclusion of the opinions that PCBs had caused respondent's lung cancer were merely "subsidiary rulings." Resp. Br. 20. The "decisive ruling" of the Court of Appeals, he says, the "key ruling," was its statement at the end of its opinion that there was a genuine issue of material fact as to exposure to furans and dioxins. Resp. Br. 19, 31. From that he says it follows that even if the Court of Appeals' reversal of the Rule 702 exclusion was improper, its judgment should nevertheless be affirmed. Resp. Br. 32-33. But the District Court's exclusion under Rule 702 of the opinions asserting PCB causation was not "subsidiary," nor was the Court of Appeals' reversal of it.[14]

Respondent claimed, and his two experts offered opinions, that he had been exposed to PCBs and that PCBs had caused or promoted his disease. J.A. 21, 112, 403, 470. They also asserted exposure to and causation by furans and dioxins. J.A. 107, 140, 143.[15] The District Court granted summary judgment on the PCB claim because it held that the opinions on PCB causation failed both the "reliability" and the "fit" requirements of Rule 702. It held that reliability was not satisfied, as noted above, because of absence of scientific methodology. P.C.A. 58a-68a. The "fit" requirement was not met either, the District Court held, because although "Plaintiffs' experts assumed Joiner was exposed to furans and dioxins" and "this assumption is an integral part of the foundation for the

[14] Respondent professes puzzlement that the Court of Appeals devoted nearly all its opinion to the admissibility of the PCB causation opinions under Rule 702. He says that "[t]he Eleventh Circuit did not explain why it addressed this issue." Resp. Br. 17 n.36. The Court of Appeals, obviously, did not share respondent's current understanding of what was the "key ruling." Its reference to possible exposure to furans and dioxins was confined to the final two paragraphs of its opinion. P.C.A. 14a-16a.

[15] Dr. Teitelbaum even was willing to opine generally that respondent's lung cancer had been caused by "the materials with which he worked," J.A. 140, 146, 470, by which term Dr. Teitelbaum said he included ordinary mineral oil and paint. J.A. 149-50, 153.

experts' opinions that PCBs contributed to Joiner's lung cancer," nevertheless "Plaintiffs have failed to show a genuine dispute over whether furans and dioxins were in the PCBs to which Joiner was exposed." P.C.A. 57a. Thus on respondent's PCB claim, the District Court held the opinions inadmissible under Rule 702 for lack of both "fit" and reliability. P.C.A. 68a. Because it held respondent had failed to present evidence creating a genuine issue of material fact that respondent had been exposed to furans and dioxins, P.C.A. 51a, the District Court did not consider whether the opinions would satisfy Rule 702 insofar as they asserted that furans or dioxins could cause or promote small-cell lung cancer.

Because the District Court's exclusion as to the claim of causation by PCBs rested alternatively on both the "fit" and reliability requirements of Rule 702, the Court of Appeals had to reject both bases for exclusion in order to reverse. That is what it did. Regarding "fit," the Court of Appeals held that whether furans and dioxins were present or not was "immaterial" to the admissibility of the opinions on PCB causation:

> "Although the terms 'PCBs,' 'dioxins,' and 'furans' often appeared together in each expert's proffered testimony, and at times the Joiners' experts asserted that it can be assumed furans and/or dioxins were present in the City's PCB-contaminated transformer fluid, it does not necessarily follow that each expert's opinion that PCB caused Joiner's cancer was contingent upon his exposure to furans or dioxins. . . . Thus, in terms of the Joiners' claim that PCB alone can cause cancer, *it becomes immaterial whether there were furans and dioxins in the fluid*."

P.C.A. 14a (emphasis supplied). Therefore, the Court of Appeals held, the District Court had no basis for ruling that the opinions on PCB causation lacked "fit." Regarding the District Court's other basis for Rule 702 exclusion—lack of reliability as science—the Court of Appeals also reversed, because, as discussed above, on "particu-

larly stringent review" it disagreed with the District Court's conclusion that the opinions lacked scientific reliability. P.C.A. 12a-13a.

The Court of Appeals added that in its view there was a genuine factual dispute "over whether furans and dioxins could have been present in the dielectric fluid." P.C.A. 15a. It never reached the question whether opinions of causation by furans or dioxins would be admissible, because the District Court had not done so.

Respondent now argues that based on the Court of Appeals' furan and dioxin exposure ruling, its entire judgment should be affirmed. Resp. Br. 31-33. That does not make sense. If, as petitioners contend, the Court of Appeals used an incorrect nondeferential standard of review in rejecting the exclusion that was the basis for the PCB judgment, then reversal of the Court of Appeals' judgment as to the PCB portion of the case is called for. This Court frequently reverses holdings that dispose of some claims in a case but not others. See, *e.g.*, *National R.R. Passenger Corp.* v. *Boston & Maine Corp.*, 503 U.S. 407, 424 (1992). Moreover, respondent until now never contended that the furan and dioxin ruling somehow controlled the whole case; his opposition to certiorari argued, to the contrary, that "the judgment below is based on the holding, under *de novo* review, that the district court applied an erroneous construction of Fed. R. Evid. 702." Br. Opp. 6 (capitals omitted). "Under this Court's Rule 15.2, a nonjurisdictional argument not raised in a respondent's brief in opposition to a petition for a writ of certiorari 'may be deemed waived.'" *Caterpillar Inc.* v. *Lewis*, 117 S. Ct. 467, 476 n.13 (1996).

CONCLUSION

For the reasons stated herein and previously, the judgment of the Court of Appeals should be reversed.

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OCTOBER TERM, 1996

GENERAL ELECTRIC CO., ET AL., PETITIONERS

v.

ROBERT K. JOINER AND KAREN P. JOINER

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONERS

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36 pp

QUESTION PRESENTED

Whether the court of appeals applied an erroneous standard of appellate review of a federal trial court's decision to admit or exclude expert scientific evidence.

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In the Supreme Court of the United States

OCTOBER TERM, 1996

No. 96-188

GENERAL ELECTRIC CO., ET AL., PETITIONERS

v.

ROBERT K. JOINER AND KAREN P. JOINER

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONERS

INTEREST OF THE UNITED STATES

As we explained in our brief as amicus curiae in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the United States is a party to a far greater number of civil cases nationwide than "even the most litigious private entity." *United States* v. *Mendoza*, 464 U.S. 154, 159 (1984). The government is also solely responsible for the enforcement of federal criminal laws. Because of the great diversity of its civil and criminal litigation, the government finds itself supporting the admissibility of scientific evidence at trial in some cases and opposing it in others. Moreover, the existence of clear standards for appellate review of particular issues materially assists the Solicitor General in determining whether to authorize appeals from adverse decisions in government

cases. See *id.* at 160-161. The United States therefore has a significant interest in the articulation of a clear, principled, and nationally applicable standard for appellate review of decisions to admit or exclude scientific evidence at trial in federal court.

STATEMENT

1. At 37, respondent Robert Joiner developed a small-cell cancer of the lung. Pet. App. 38a. Respondents sued petitioners on the theory that early onset of the disease was caused by exposure to polychlorinated biphenyls (PCBs) and to PCB-derived polychlorinated dibenzofurans (furans) and polychlorinated dibenzodioxins (dioxins) contained in products manufactured by petitioners (*id.* at 35a-36a, 39a).

From 1973 until the time of trial, respondent worked as an electrician for the City of Thomasville, Georgia. Pet. App. 35a. Although the technology used in the city's electrical transformers should have made them free of PCBs throughout his employment, testing conducted between 1983 and 1993 revealed that approximately 20% contained PCBs at a level recognized as contaminating by the Environmental Protection Agency.[1] *Id.* at 36a-37a. Respondent alleged that he was exposed to PCBs or their derivatives while maintaining the city's transformers, through contact with the fluid used to cool and insulate them or with fumes released when transformer cores were "baked off" under high heat. *Id.* at 37a.

2. The district court granted summary judgment for petitioners. Pet. App. 34a-69a. The court recognized a factual dispute over whether respondent was

[1] See 40 C.F.R. 761.3 (*s.v.* "PCB-Contaminated Electrical Equipment"). Since 1978, the manufacture, sale, and use of PCBs has been severely restricted and subject to regulation by the EPA. See 15 U.S.C. 2605(e)(2)(A); 40 C.F.R. Pt. 761.

exposed to PCBs (*id.* at 44a), but held that there was insufficient evidence to raise a genuine issue of fact concerning exposure to furans or dioxins (*id.* at 49a, 51a). The court found no evidence that furans were created in the "bake off" process or through transformer fires, because respondent had not shown that either situation produced the necessary temperatures. *Id.* at 49a. The court also found respondents' evidence insufficient to raise a factual issue concerning whether dioxins were present in the transformer fluids with which respondent had worked. *Id.* at 49a-51a.

The court held (Pet. App. 51a-68a) that expert testimony proffered by respondents to establish that PCB exposure caused the onset of Robert Joiner's lung cancer was inadmissible under Federal Rule of Evidence 702, as construed by this Court in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The court concluded that the testimony did not "fit" the facts of this case, because the experts' opinions concerning causation were "inextricably bound up with [their] assumption that [respondent] was exposed to furans and dioxins" (*id.* at 53a)—an assumption the court had held lacked evidentiary support. *Id.* at 57a.

The court further held that the proffered opinions would be inadmissible even without that assumption, because they were not sufficiently reliable under *Daubert*. Pet. App. 58a-67a. The court rejected the experts' reliance on two animal studies because respondents did not demonstrate the applicability of those studies to human beings or to PCB exposure at the level relevant to respondents' case. *Id.* at 58a-62a. After considering the epidemiological studies cited by respondents (*id.* at 62a-67a), the court concluded that they were "equivocal or not helpful to [respondents]"

(*id.* at 63a). In sum, the court was "not persuaded by a preponderance of proof that the studies [cited by respondents] support the 'knowledge' the experts purport to have, i.e., that PCBs, to a reasonable degree of medical certainty, promote small cell lung cancer in humans." *Id.* at 67a (citation and internal quotation marks omitted). Because "[t]he analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue" of causation was "too wide," the court concluded that the proffered expert opinions did not "rise above subjective belief or unsupported speculation," and were not admissible. *Ibid.*

Because, in the absence of expert opinions, respondents had submitted no tenable evidence of causation, the district court granted petitioners' motion for summary judgment. Pet. App. 68a.[2]

3. The court of appeals reversed. Pet. App. 1a-16a. With regard to the district court's evidentiary ruling, the court first noted that "[a] district court's ruling on the admissibility of evidence is reviewed for abuse of discretion," but it then held that, "[b]ecause the Federal Rules of Evidence governing expert testimony display a preference for admissibility," it would "apply a particularly stringent standard of review to the trial judge's exclusion of expert testimony." *Id.* at 4a.

The court did not separate its discussion of summary judgment and admissibility issues. Considering

[2] The court further noted its belief that "no reasonable juror could find that PCBs caused [Robert] Joiner's lung cancer given the flawed nature of [respondents'] experts' opinions," so that "[s]ummary judgment for [petitioners] would be in order even if" the expert testimony were admissible. Pet. App. 67a n.29.

first the question of "reliability" under *Daubert*, the court recited the qualifications of respondents' experts, described their general methodology, and noted that each had "asserted the general acceptance of the procedures [he] employed." Pet. App. 8a-11a. The court acknowledged that "[t]he assessment of reliability also involves reviewing the basis for an expert's opinion" (*id.* at 11a), but it criticized the district court for rejecting the experts' reliance on the cited animal studies (*id.* at 11a-12a), for limiting its consideration to the studies discussed in the district court's opinion (*id.* at 12a-13a), and for "accept[ing] [petitioners'] criticisms of the conclusions reached in those studies" (*id.* at 13a). In the court of appeals' view, the district court exceeded proper bounds by ruling on the "correctness" of the proffered expert opinions. *Ibid.*

With respect to "relevance" under *Daubert*, the court held that the opinions of respondents' experts did not depend on exposure to furans or dioxins and that, based on its review of the record, there "appear[ed] to be a genuine factual dispute as to whether PCBs alone can cause cancer." Pet. App. 14a. The court also held that a genuine dispute did exist over "whether furans and dioxins could have been present" in the fluids to which respondent was exposed (*id.* at 14a-15a), because one of respondents' experts had stated that the "baking off" process might reach a temperature of 700-800 degrees centigrade. The court concluded that "the testimony of [respondents'] experts was erroneously excluded and summary judgment should not have been granted." *Id.* at 16a.

Judge Birch concurred "specially" (Pet. App. 16a-17a), on the ground that the court's opinion "properly emphasize[d] the role of the district court as 'gate-

keeper'" with respect to proffered scientific testimony. Judge Smith dissented (*id.* at 17a-30a), concluding that the "trial court properly applied *Daubert* and did not abuse its discretion in ruling certain expert testimony inadmissible." *Id.* at 29a-30a.

SUMMARY OF ARGUMENT

The question in this case is what standard an appellate court should use in reviewing a district court's decision to admit or exclude expert scientific testimony. No statute or rule directly answers that question, but several considerations suggest that such a decision should be reviewed only for abuse of discretion. First, the text of Rule 702 of the Federal Rules of Evidence suggests that result. Second, trial courts are generally accorded wide discretion in determining the admissibility of evidence, and there is no justification for a basically different rule here. Third, institutional factors counsel in favor of deferential review. The preliminary assessment of proffered scientific evidence required by Rule 702 will often require a detailed and fact-specific analysis, made in the context of a particular case and at a particular point in the proceedings. The district court is better positioned to undertake that analysis. Moreover, there is no reason to believe that appellate judges will be systematically better able to evaluate the relevance or reliability of scientific testimony in close cases. Thus, the incremental accuracy that might be achieved through review under a standard more stringent than abuse of discretion would not likely be worth the costs that such review would entail.

Discretionary decisions, however, are not left to a district court's inclination, but to its judgment, and the courts of appeals have an important role to play in

ensuring that that judgment is appropriately exercised. Appellate courts may always correct material errors of law or clear errors of fact, because basing a decision on either type of error will always be an abuse of discretion. In other cases, the district court may have failed to exercise its discretion, in which case some appellate remedy will generally be appropriate. Sometimes, it will be appropriate for a court of appeals to review an accumulated body of knowledge and experience and to rule that a particular type of evidence is generally either acceptable or unacceptable as a categorical matter. Finally, the court of appeals must ensure that the district court's discretionary determinations in any case stay within the limits of permissible judgment. Those limits defy concise definition. Bearing in mind the institutional considerations we have mentioned, however, the court of appeals should be reluctant to undertake an extensive independent examination of the issues or record involved, and wary of concluding that it is in a better position than the district court to evaluate the reliability and relevance of proffered evidence in the context of a particular case.

Application of these principles to this case is complicated by the fact that the district court's grant of summary judgment was based only in part on its exclusion of respondents' experts' opinions concerning causation. Even if we assume, however, that the court of appeals correctly held that the case presented a genuine factual issue with respect to exposure to furans and dioxins, the district court's judgment should have been affirmed. That court did not base its decision with respect to causation on any clear error of fact, and it undertook the proper

inquiry with respect to respondents' scientific evidence. Although the question will always be a close one in any case in which the standard of review is likely to make a difference, we think the district court's conclusion that the proffered evidence was not sufficiently relevant or reliable to be admitted to prove the ultimate issue of causation was a permissible one. The court of appeals therefore should not have disturbed it on appeal.

ARGUMENT

I. A TRIAL COURT'S DECISION TO ADMIT OR EXCLUDE SCIENTIFIC EVIDENCE SHOULD BE REVIEWED FOR ABUSE OF DISCRETION

As this Court explained in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), the Federal Rules of Evidence "assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." In other words, they give the judge "the responsibility for keeping 'junk science' out of the courtroom." *Wilson* v. *City of Chicago*, 6 F.3d 1233, 1238 (7th Cir. 1993), cert. denied, 511 U.S. 1088 (1994). In discharging that "gatekeeping role" (*Daubert*, 509 U.S. at 597), a district court must (i) understand the requirements of the Rules, as interpreted by this Court in *Daubert*; (ii) find any facts necessary to decide threshold issues relating to admissibility (see Fed. R. Evid. 104(a)); and (iii) make "a preliminary assessment of whether the reasoning or methodology underlying the [proffered] testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue" (*Daubert*, 509 U.S. at 592-593). The question

presented in this case is how an appellate court should review the district court's determinations.[3]

No statute or rule directly answers that question. Several considerations suggest, however, that an appellate court should not substitute its judgment for that of the district court on these issues, but should instead determine whether, under governing legal principles, the trial court has abused its discretion.

1. The Federal Rules of Evidence are to be interpreted like any other statute. *Daubert*, 509 U.S. at 587. Rule 104(a) provides that "[p]reliminary questions concerning * * * the admissibility of evidence shall be determined by the court." See *id.* at 592 & n.10. This Court has observed elsewhere that, when Congress explicitly commits an issue to decision by "the court," rather than simply providing a rule of decision, the statutory formulation "emphasizes the fact that the determination is for the district court to make, and thus suggests some deference to the district court on appeal." *Pierce* v. *Underwood*, 487 U.S. 552, 559 (1988) (construing 28 U.S.C. 2412(d)(1)(A)). The same is true here.

2. As a general matter, "[a] district court is accorded a wide discretion in determining the admissibility of evidence under the Federal Rules." *United States* v. *Abel*, 469 U.S. 45, 54 (1984).[4] This Court has

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[3] It is possible to articulate a standard of review for each part of the overall inquiry. See, *e.g.*, Pet. App. 18a (Smith, J., dissenting). It is simpler, however, to treat errors of law or fact as aspects of abuse of discretion, as this Court has done in other contexts. See pages 17-19, *infra*; *Cooter & Gell* v. *Hartmarx Corp.*, 496 U.S. 384, 399-405 (1990).

[4] Before the adoption of the Rules, this Court had indicated that deferential review was appropriate for rulings concerning the admissibility of expert testimony. *Salem* v. *United States Lines Co.*, 370 U.S. 31, 35 (1962) (dictum) ("[T]he trial judge

applied that principle specifically to rulings determining relevance (Rule 401) and balancing probative value against the risk of unfair prejudice (Rule 403). *Id.* at 54-55; *Old Chief* v. *United States*, 117 S. Ct. 644, 647 n.1, 651 n.7 (1997). "Relevance" is a central part of the inquiry concerning the admissibility of scientific evidence under Section 702. *Daubert*, 509 U.S. at 587, 591, 597. Similarly, because of the powerful and potentially misleading nature of scientific evidence, a district court will typically "exercise[] more control over experts than over lay witnesses" under Rule 403. *Id.* at 595 (quoting Weinstein, *Rule 702 of the Federal Rules of Evidence Is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 632 (1991)). In the case of scientific evidence, the court's determinations regarding probative value and unfair prejudice under Rule 403 are likely to be closely related to its determinations, under Rule 702, concerning reliability and relevance. It would make little sense to apply a basically different standard of appellate review to one set of decisions than to the other.

For similar reasons, there is no force to the court of appeals' assertion (Pet. App. 4a) that the Rules manifest a "preference for admissibility." While the Rules may have a "liberal thrust," manifested in this context by "relaxing the traditional barriers to 'opinion' testimony" (*Daubert*, 509 U.S. at 588), *Daubert* itself demonstrates that no general rule justifies the admission of scientific testimony that is not reliable or does not "fit" the case at hand. Moreover, whatever the rule at trial, a general "preference

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has broad discretion in the matter of the admission or exclusion of expert evidence, and his action is to be sustained unless manifestly erroneous."); *Spring Co.* v. *Edgar*, 99 U.S. 645, 658 (1878) (dictum) (same).

for admissibility" operative at the appellate level would preclude reviewing courts from ever deferring to rulings excluding evidence. That has plainly never been the rule.

3. This Court has frequently recognized that the standard of appellate review appropriate to a particular sort of decision may depend on "the respective institutional advantages of trial and appellate courts." *Salve Regina College* v. *Russell*, 499 U.S. 225, 233 (1991); see also *Koon* v. *United States*, 116 S. Ct. 2035, 2046-2048 (1996); *Ornelas* v. *United States*, 116 S. Ct. 1657, 1662-1663 (1996); *Cooter & Gell* v. *Hartmarx Corp.*, 496 U.S. 384, 399-405 (1990); *Pierce*, 487 U.S. at 559-561; *Miller* v. *Fenton*, 474 U.S. 104, 112-118 (1985). In our view, district courts are better positioned than appellate courts to make the preliminary assessment of scientific validity and factual relevance required by *Daubert* (see 509 U.S. at 592-593).

a. That assessment will frequently require a detailed analysis of the nature of the proffered evidence; the scientific and factual premises on which it rests; whether those premises are well established, conjectural, or something in between; and what logical chain of reasoning connects general knowledge or principles to the facts and circumstances that a party proposes to establish in the particular case before the court. See generally *Daubert*, 509 U.S. at 593-595. To inform its analysis, the district court may seek clarification or hear argument from the parties; and in close or complicated cases it may examine the proffered experts, or even seek the assistance of an independent expert of its own choosing. See *id.* at 595; Fed. R. Evid. 706.

Based on its inquiry, the court must decide whether proffered scientific evidence is or is not

"scientific * * * knowledge" for purposes of Rule 702—that is, whether or not the proposed inferences or assertions are scientifically derived and "supported by * * * 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590. That decision is essentially a factual one. The court must also decide whether the evidence will "assist the trier of fact" (Fed. R. Evid. 702). That question, which "goes primarily to relevance," is "one of 'fit'" between the proffered evidence and the facts and issues of the case before the court. *Daubert*, 509 U.S. at 591.

To the extent that the judicial assessment of reliability and relevance required under *Daubert* rests on an essentially factual inquiry, it is the product of a process in which district courts have "unchallenged superiority" over courts of appeals. *Salve Regina*, 499 U.S. at 233; see *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574-575 (1985). To the extent that the inquiry is intertwined with legal issues (as, for instance, in assessing relevance), the district judge, who is "[f]amiliar with the issues and litigants" (*Cooter & Gell*, 496 U.S. at 402), and who is intimately involved with the case *at the time that the relevant assessment must be made*, will generally be "better situated than the court of appeals to marshal the pertinent facts and apply the fact-dependent legal standard" (*ibid.*). See also *id.* at 403-404; *Pierce*, 487 U.S. at 560-561; compare *Daubert*, 509 U.S. at 591 (discussing evidentiary "fit"). For these reasons, the question of admissibility of proffered scientific evidence seems to us more like the appropriateness of Rule 11 sanctions, at issue in *Cooter & Gell*, or whether a legal position taken during litigation was "substantially justified," considered in *Pierce*, 487

U.S. at 561, than like the questions of controlling substantive law at issue in *Salve Regina*.[5]

b. A decision on expert testimony may itself have a significant impact on the length, nature, and cost of an action. It may also shape other important decisions by the court and the parties. Thus, it will often be an integral part of the district court's overall supervision and management of the litigation. Such supervisory decisions, like factual or heavily fact-dependent determinations, have typically been left to the district court's sound discretion. See *Salve Regina*, 499 U.S. at 233; *Cooter & Gell*, 496 U.S. at 404; *Pierce*, 487 U.S. at 558 n.1. Often, they may be disturbed on appeal only at significant cost, not only in terms of the immediate action (which will presumably have to be tried or retried on remand), but in broader systemic terms as well.

As this Court has emphasized, when an appellate court reviews factual findings,

> [t]he rationale for deference to the original finder of fact is not limited to the superiority of the trial judge's position to make determinations of credibility [of witnesses]. The trial judge's major role is the determination of fact, and with experience in

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[5] Plenary appellate review of certain factual or "mixed" questions may be appropriate when the issue involved is one of transcendent constitutional importance, or when a constitutional standard can "acquire content only through application." *Ornelas*, 116 S. Ct. at 1662 ("probable cause" and "reasonable suspicion"); *Hurley* v. *Irish-American Gay, Lesbian & Bisexual Group of Boston*, 115 S. Ct. 2338, 2344 (1995) (whether conduct is expressive for First Amendment purposes); *Miller* v. *Fenton*, 474 U.S. at 112-118 (whether confession was "voluntary"); *Bose Corp.* v. *Consumers Union of United States, Inc.*, 466 U.S. 485, 502 (1984) ("actual malice"). Those concerns are not present in this context.

> fulfilling that role comes expertise. Duplication of the trial judge's efforts in the court of appeals would very likely contribute only negligibly to the accuracy of fact determination at a huge cost in diversion of judicial resources.

Anderson v. *City of Bessemer City*, 470 U.S. at 574-575. The same will be true of most determinations with respect to admissibility under Rule 702. Threshold determinations of the admissibility of evidence of all kinds are an ordinary incident of the trial judge's role, and "with experience * * * comes expertise." The details of a particular scientific theory, study, or technique may be unfamiliar to the district court, but the principles of relevance and reliability are not. There is, moreover, no reason to think that the scientific details pertinent to a particular case will be any more familiar to the judges who sit on the courts of appeals.

This point must be emphasized, for it has been argued that "more stringent" review is appropriate in the context of scientific evidence because "evaluating the reliability of scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses and thus is often not significantly more difficult on a cold record." *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 749 (3d Cir. 1994), cert. denied, 115 S. Ct. 1253 (1995); see Pet. App. 4a-5a. That argument underestimates the value of a district court's ability to evaluate the "credibility" of a witness, including an expert witness at a hearing on admissibility.[6] Even with respect to cases decided

[6] In the case of expert witnesses, "credibility" involves considerably more than "truthfulness." Some experts are zealous in pursuit of the truth, while others may be zealous primarily in pursuit of some personal, professional, or political agenda. Some may lack perceptible zeal. Such qualities tend to emerge in live testimony. They are often harder to perceive or evaluate on a "cold record."

purely on a paper record, however, the argument slights the role of the district court in the overall judicial "project of reaching a quick, final, and binding legal judgment" (*Daubert*, 509 U.S. at 597). The pertinent point is not that appellate courts are less competent to evaluate scientific evidence than the district court, but that there is little reason to think they will be systematically any *more* competent to do so.

No judge may be presumed to have pre-existing familiarity with whatever principles, techniques, or other technical background material may be relevant to the scientific evidence offered in a particular case. The district court must expend whatever resources are necessary to achieve sufficient familiarity to discharge its responsibilities under Rule 702. Similarly, the judges of the court of appeals must familiarize themselves with the relevant materials to the extent necessary to review a challenged ruling on admissibility.

At the appellate level, however, there will often be a significant difference between the effort required to conclude that the district court discharged its duty of inquiry and reached a permissible decision, and the effort required to subject the trial court's decision to a "hard look" (*In re Paoli R.R. Yard*, 35 F.3d at 749) or to "particularly stringent * * * review" (Pet. App. 4a). See also *Pierce*, 487 U.S. at 560 ("[E]ven where the district judge's full knowledge of the factual setting can be acquired by the appellate court, that acquisition will often come at unusual expense."). Because the courts of appeals sit in panels,

that incremental cost must be multiplied by three. Finally, because an abuse-of-discretion standard will already, by hypothesis, result in the correction of evidentiary errors that are both serious and prejudicial, the benefits to be derived from "particularly stringent" review are only those that may arise from changing permissible decisions to preferable ones. Thus, the "[d]uplication of the trial judge's efforts in the court of appeals [will] very likely contribute only negligibly to the accuracy" of rulings under Rule 702, "at a huge cost in diversion of judicial resources." *Anderson*, 470 U.S. at 574-575; compare *Salve Regina*, 499 U.S. at 231-233 (independent appellate review on controlling questions of substantive law).

Deference to the trial court's evidentiary rulings, like deference to its rulings under Rule 11, will tend to enhance the ability of "courts on the front lines of litigation * * * to control the litigants before them," and will "discourage litigants from pursuing marginal appeals, thus reducing the amount of satellite litigation." *Cooter & Gell*, 496 U.S. at 404. "Stringent" or "hard look" review (Pet. App. 4a), on the other hand, risks turning the district court's consideration of scientific evidentiary issues into "a 'tryout on the road,'" with appellate briefing and argument "the 'main event.'" *Anderson*, 470 U.S. at 575 (quoting *Wainwright* v. *Sykes*, 433 U.S. 72, 90 (1977)).[7] Appellate courts have an important role to

[7] See the 67-page opinion in *In re Paoli Railroad Yard PCB Litigation*, which originated the "more stringent review" standard adopted by the court of appeals in this case (Pet. App. 4a-5a). Compare the recent decision by the same court in *In re Paoli Railroad Yard PCB Litigation*, No. 95-2098 (3d Cir. May 12, 1997), slip op. 19 (according "particular deference" to

play in policing the boundaries of discretion under Rule 702 and *Daubert*, as we discuss below. That role is not, however, to afford disappointed parties an opportunity to relitigate at the appellate level close evidentiary questions appropriately considered and resolved by the district court.

II. AN ABUSE-OF-DISCRETION STANDARD ALLOWS FOR APPELLATE INTERVENTION IN APPROPRIATE CASES

Review for abuse of the district court's discretion is "not * * * an empty exercise." *Koon* v. *United States*, 116 S. Ct. at 2046. "[D]iscretionary choices are not left to a court's 'inclination, but to its judgment, and its judgment is to be guided by sound legal principles.'" *Albemarle Paper Co.* v. *Moody*, 422 U.S. 405, 416 (1975) (quoting *United States* v. *Burr*, 25 F. Cas. 30, 35 (C.C. Va. 1807) (No. 14,692d) (Marshall, C.J.)). There are several situations in which it will be appropriate for an appellate court to intervene to provide the necessary legal guidance. Although general categories can only be suggestive, and will frequently overlap, they may be usefully summarized as follows.

A. Errors Of Fact Or Law

Appellate courts are, preeminently, expositors of the law. See, *e.g.*, *Salve Regina*, 499 U.S. at 231-233. If a district court has failed to perform the sort of relevance and reliability analysis required by *Daubert*, thereby failing to discharge its "gatekeeper" role under Rule 702, then the appellate court may properly vacate the decision below and remand

district court's decision to exclude certain expert testimony under Rule 403); see page 10, *supra*.

the case with instructions to the district court to exercise its discretion under the proper legal standards. Similarly, if a trial court's decision to exclude scientific evidence can be shown to have been based on a misunderstanding of the applicable substantive law, an appellate court will be well positioned to correct the underlying legal error, and accordingly reverse or vacate the associated evidentiary ruling.[8] The

[8] This might be the case if the district court did not appreciate the relevance of proffered evidence under the governing law, or if it misunderstood the degree of scientific certainty required to satisfy an applicable legal standard. For example, the proof of causation that the plaintiff must offer in a tort action such as this one is significantly different from the demonstration of *risk* that often permits or requires government action in the environmental or public health context. Thus, important environmental statutes require government action upon a showing that a condition creates a "danger" or "risk" of specified consequences. See, *e.g.*, 42 U.S.C. 6973(a) ("imminent and substantial endangerment to health or the environment"), 9606(a) ("substantial endangerment to the public health or welfare or the environment"). Other statutes provide that facts may be established pursuant to a specified standard, even where the scientific community has not reached a uniform conclusion under that standard or where the standard itself calls for cutting-edge science or technology. See 42 U.S.C. 7475(a)(4) (requiring installation under the Clean Air Act of the "best available control technology"), 7479(3) (defining "best available control technology"), 7501(3) (defining "lowest achievable emission rate"); 21 U.S.C. 348(c)(3)(A) ("no [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal"). In such circumstances, expert testimony showing that the scientific community is significantly divided would be sufficiently reliable to be admitted to establish the existence of a risk meeting the statutory standard. While the standard of appellate review in such a case would be the same, the substantive legal standard against which to assess the district court's decision would be significantly different.

same applies to clear factual errors that can be shown to have affected an evidentiary ruling (for example, a finding that a particular theory has never been subject to peer review, when the record contains three published articles on the subject in peer-reviewed journals). In such cases, the district court's error of fact or law would amount to an abuse of discretion, and would plainly be subject to correction by the court of appeals. See, *e.g.*, *Koon*, 116 S. Ct. at 2047-2048; *Cooter & Gell*, 496 U.S. at 401-402, 405; see also *United States* v. *Jones*, 107 F.3d 1147, 1150-1156 (6th Cir. 1997).

B. Failure To Exercise Discretion

An appellate court cannot review for abuse of discretion if the district judge did not exercise discretion in the first place. In a few cases the district court may so misapprehend its role, undertake so inadequate an inquiry, or offer so inadequate an explanation for its ruling on admissibility that the court of appeals will find itself unable to discern the grounds for that ruling or how they relate to the factors that the trial court was required to take into account under Rule 702 and *Daubert*. Some remedy will generally be appropriate in such cases, ranging from de novo determination of the issue (if, for example, the relevant materials are in the record, the issues are clear, and there is no other reason to remand the case) to a remand with instructions to undertake the appropriate evidentiary inquiry.

C. Categorical Determinations

One argument in favor of active appellate review of issues involving the admissibility of scientific evidence is that such review will promote a desirable uniformity in the law. That argument is not persua-

sive as a general matter, because many or most of the issues that generate significant controversy in actual cases are likely to involve unsettled scientific principles, questions of methodology or competence relating to studies or tests performed especially for a particular litigation, or the questionable application of known principles to "a particular set of events in the past." *Daubert*, 509 U.S. at 597.[9] They will therefore tend to involve the sort of "multifarious and novel question, little susceptible, for the time being at least, of useful generalization," which is best left largely to the sound discretion of the district court. *Pierce*, 487 U.S. at 562; see *Cooter & Gell*, 496 U.S. at 404-405.

There are, however, limited circumstances under which it will be appropriate for an appellate court to settle, for proceedings within its jurisdiction, a recurrent issue involving the admissibility of scientific evidence. As Judge Friendly observed, the scope of permissible discretion with respect to specific issues may appropriately narrow over time:

> The rulemakers gave the district courts discretion; but after enough of them had decided always to exercise it the same way, a way that the court of appeals deemed appropriate, the channel of discretion had narrowed, and a court of appeals

[9] The evidentiary controversy in this case, for example, involved both whether exposure to PCBs, per se, had been linked to the development of cancer in human beings (a matter of unsettled scientific principle), and whether presumably valid studies showing that PCBs, furans and/or dioxins caused certain cancers in high-dose animal studies were sufficiently relevant to Robert Joiner's individual experience to be admissible to show the cause of his cancer.

> should keep a judge from steering outside it rather than allow disparate results on the same facts.

Friendly, *Indiscretion About Discretion*, 31 Emory L.J. 747, 772 (1982). That principle will apply, in certain circumstances, to questions concerning the scientific reliability of particular theories, tests, studies, or other types of expert evidence potentially admissible under Rule 702.

Although "[s]cientific conclusions are subject to perpetual revision" (*Daubert*, 509 U.S. at 597), it is also true that "theories that are so firmly established as to have attained the status of scientific law, such as the laws of thermodynamics, properly are subject to judicial notice" (*id.* at 592 n.11). In the progression from novel idea to scientific "law," a particular theory or technique will undergo a process of scientific and judicial testing. In the early stages, disparate results are predictable; and, in the judicial context, there is no reason to think that appellate consideration of the first case in which admission of evidence based on a new theory is sought should control the matter for the future.

After some period of time, however, with increasing experience (both scientific and judicial), there will often come a point when the balance of efficiency tips, and an appellate court may usefully review the available evidence and conclude that a given technique, in a definable set of circumstances, is either so thoroughly established or so thoroughly discredited that further case-by-case consideration of the issue would not be a productive use of judicial resources. That result is consistent both with *Daubert* and with the general use of an abuse-of-discretion standard.[10]

[10] Of course, in any given case, the trial judge will still have to consider challenges to the way that an expert uses an

D. Exceeding The Permissible Limits Of Discretion

The foregoing bases for review are relatively easily described, and not likely to be controversial. There remains, however, the case of the district court that has understood its role, reviewed seriously the materials provided to it by the parties, analyzed without obvious legal or factual error the proffered evidence's scientific reliability and its relevance to the pending case, and reached a conclusion concerning admissibility that is seriously challenged on appeal, and that the court of appeals finds at least superficially troubling.

It is not self-evident what it means to say that a court of appeals should review such a decision for "abuse of discretion." At a minimum, that phrase means that the lower court has a range of permissible choices, and that its decision should not be disturbed so long as it stays within that range. *E.g.*, *United States* v. *Dockery*, 955 F.2d 50, 54 (D.C. Cir. 1992); *Barnett* v. *Equitable Trust Co.*, 34 F.2d 916, 920 (2d Cir. 1929) (L. Hand, J.), aff'd as modified, 283 U.S. 738 (1931); compare *Anderson*, 470 U.S. at 574 ("Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous."). Put differently, the appellate court should not reverse a discretionary decision unless it can say that its review of the matter "commands" the opposite conclusion. *Pierce*, 487 U.S. at 570. In the end, however, such phrases can do little more than restate the question of how much discretion the reviewing court is prepared to accord the court reviewed.

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accepted technique or theory, or to whether evidence based on unexceptionable science is sufficiently relevant to the facts of the matter at hand.

In the present context, we think that question is best addressed in light of the considerations of comparative institutional advantage and judicial efficiency discussed above. As this Court emphasized in *Daubert*, 509 U.S. at 597, the object of the overall judicial enterprise is not an "exhaustive search for cosmic understanding," but appropriate delivery of "a quick, final, and binding legal judgment." Naturally, it is also important to strive for "decisional accuracy"; and appellate review on almost any issue will tend to promote that goal. *Salve Regina*, 499 U.S. at 232. But it will promote it only at considerable cost. Courts of appeals should be wary of deciding that they are in a better position than trial courts to evaluate the reliability and relevance of proffered scientific evidence in most cases; and they should be reluctant to undertake an extensive independent review of the issues or record involved.

Moreover, it is appropriate to place considerable responsibility on the parties in this regard. A party proffering (or challenging) scientific evidence in the district court should take care to provide that court with a clear and adequate submission, including copies of relevant materials, that specifically delineates how the evidence meets (or does not meet) the reliability and relevance criteria articulated in *Daubert*. Similarly, on appeal, a party challenging an admissibility decision ordinarily should be able to point specifically and succinctly to a particular analytical error that so fundamentally taints the court's decision as to require reversal. We suspect that parties that have adequately presented their case to the district court will seldom be able to point to such an error on appeal. Parties that have failed to present their case adequately below will not ordinarily merit rescue by the court of appeals.

III. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION IN EXCLUDING THE TESTIMONY OF RESPONDENTS' EXPERTS

Application of these principles in this case is complicated by the fact that the district court's grant of summary judgment was based only in part on the inadmissibility of expert testimony. An order granting summary judgment is reviewed de novo, resolving all factual questions in favor of the non-moving party. See Pet. App. 4a. Yet, what facts are at issue may materially affect the district court's analysis of proffered scientific evidence.

In this case, the district court ruled that there was a genuine issue concerning Robert Joiner's exposure to PCBs, but no issue with respect to his exposure to furans or dioxins. Pet. App. 44a, 49a, 51a. With respect to furans and dioxins, the court considered the testimony of respondents' experts, but held that it did not suffice to create an issue for trial. *Id.* at 47a-48a, 50a-51a. Thus, the court of appeals' reliance on the experts' testimony in reversing on that issue (*id.* at 14a-16a) did not depend on rejecting any evidentiary ruling made by the district court. Because this Court granted review to consider only the evidentiary question (Pet. i), we assume here that respondents have adequately raised a factual issue concerning Robert Joiner's exposure to furans and dioxins.[11]

[11] For the same reason, we do not suggest that the Court rest its decision on the district court's passing observation (see note 2, *supra*) that it would have granted summary judgment for petitioners even if it had not excluded the scientific evidence proffered by respondents. To the extent that observation amounted to an alternative ground for the district court's decision, it presents a materially different issue concerning the standard of appellate review than does the court's admissibility ruling.

The question presented is therefore whether, if we assume Joiner's exposure to PCBs, furans or dioxins, the district court abused its discretion in concluding that the expert opinions proffered by respondents to prove that it is more likely than not that one or more of those substances contributed, to a "reasonable degree of medical certainty," to the early onset of Joiner's small-cell lung cancer were not sufficiently reliable or relevant to be submitted to a jury. See Pet. App. 51a. Respondents proffered two expert opinions on causation, based in each case on the experts' general background and experience and on specific animal and epidemiological studies. See *id.* at 8a-10a, 53a-68a. Taking into account the considerations outlined above, we conclude that the court of appeals should not have disturbed the district court's conclusions in this case.

1. First, the court of appeals was entitled to review for clear errors of fact or law affecting the district court's ruling. Because it reversed the trial court's holding that there was no genuine issue of fact concerning respondent's exposure to furans or dioxins, the court of appeals could properly conclude that it should also reverse the admissibility ruling to the extent that it relied on the observation that the proffered opinions were "inextricably bound up with the experts' assumption that Joiner was exposed to furans and dioxins." Pet. App. 53a; see *id.* at 53a-57a. The ruling that the proffered testimony "manifestly does not fit the facts of this case" (*id.* at 57a) was based on a view of the facts that was clearly incorrect in light of the appellate court's independent ruling on summary judgment, and it therefore cannot remain a permissible ground for exclusion under Rule 702.

The court of appeals implied (Pet. App. 11a-13a) that its reversal of the district court's "reliability" deter-

minations was similarly based on a clear error of law, because the district court misunderstood its role under *Daubert* and improperly focused on the proffered experts' "conclusions" rather than on their "principles and methodology." *Id.* at 13a (quoting *Daubert*, 509 U.S. at 595). That sort of legal error would be a proper ground for reversal under an abuse-of-discretion standard. We disagree, however, with the court of appeals' view that the district court misunderstood its role in this case.

The district court properly recited the basic standards set out in *Daubert*. See Pet. App. 53a, 67a. After thoroughly reviewing the materials cited to it by petitioners and respondents (see *id.* at 53a-67a), the court determined, not that the conclusions urged by respondents' experts were incorrect or inherently implausible (cf. *id.* at 63a n.26), but that the "analytical gap" between those conclusions and the scientific materials on which they purportedly relied was simply "too wide" (*id.* at 67a, quoting *Turpin* v. *Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir.), cert. denied, 506 U.S. 826 (1992)), so that they amounted to no more than "subjective belief or unsupported speculation" (*ibid.*). That is precisely the inquiry not only authorized, but mandated, by *Daubert*. See 509 U.S. at 589-590 & n.9 (Rule 702 imposes standard of "evidentiary reliability" and "trustworthiness"; court should not admit expert testimony unless it is "supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known"). If the district court abused its discretion, it did so by reaching the wrong conclusion in its analysis, not by misunderstanding or stepping outside the "gatekeeping" role assigned to it by *Daubert*.

2. For the same reason, this is not a case in which the district court failed to exercise its discretion.

Nor is it a case in which it would have been appropriate for the court of appeals to pronounce categorically on a particular scientific evidentiary issue, and the court did not purport to do so. Thus, of the criteria for appellate decision that we have identified, there remains only the question whether the district court abused its discretion by concluding that the proffered testimony of respondents' experts as to causation was not sufficiently reliable to be admitted and considered by the jury.

We think the trial court's conclusion was a permissible one. With respect to studies showing the development of cancer in mice exposed to PCBs, the court noted (Pet. App. 59a, 61a) that the two cited studies were "preliminary" in nature, and showed only that "massive doses" of PCBs, injected directly into the peritoneum or stomach of suckling mice that had been previously dosed with a known initiating carcinogen, could promote the development of dose-dependent tumors of a type different from the small-cell carcinoma found in respondent Joiner's lungs. In attempting to answer these concerns, respondents "addresse[d] the question of reliance on animal studies in general, not the deficiencies that [petitioners] * * * highlighted in the experts' reliance on the animal studies at issue here." *Id.* at 62a. In the absence of an adequate supplementary showing (compare *id.* at 62a n.25) demonstrating, at a minimum, (i) that human beings behave similarly to the tested animals when exposed to a potential carcinogen and (ii) that there was some basis for extrapolating from the high dosage tested in the animal studies to the much lower exposure levels that might actually have been shown by the evidence in this case, the district court could reasonably hold that causation opinions based primarily on these studies were not sufficiently

reliable to be admitted. See *In re Paoli R.R. Yard*, 35 F.3d at 743 ("there must be good grounds to extrapolate from animals to humans").

Similarly, after carefully reviewing (Pet. App. 63a-67a) the epidemiological evidence provided to it by respondents in opposing petitioners' motion for summary judgment (see *id.* at 62a-63a), the court concluded (*id.* at 67a) that the cited materials could not support the opinions proffered by respondents' experts on the ultimate issue of causation in this case. The district court questioned the support provided by a study on cancer mortality among capacitor workers, for example, because the study itself found "no grounds for associating lung cancer deaths * * * and exposure in the plant," cautioned that "[t]he numbers were small, [and] the value of the risk estimate was not statistically significant," and suggested only "the plausibility of a carcinogenic action." *Id.* at 63a & n.26. Another study showed no statistically significant effect on mortality from lung cancer (*id.* at 64a), while a third showed an increase in lung-cancer deaths but had nothing to do with PCB exposure (*id.* at 64a-65a). The remaining study cited by respondents evidently did not control for cigarette smoking or other relevant variables, involved PCB, furan and dioxin contamination of rice oil used to cook food in Japan, and was characterized by one of respondents' own experts as "suggestive" but "not very convincing." *Id.* at 65a-66a.

The court of appeals criticized the district court's ruling on the grounds that the lower court (i) mentioned the low number of animal studies, (ii) "f[ound] research unreliable solely because it use[d] animal subjects," (iii) specifically discussed only a limited number of studies cited by respondents' experts, and (iv) impermissibly "excluded the testimony because

[the court] drew different conclusions from the research than did each of the experts," who were well qualified, and each of whom maintained that he had used "scientifically reliable methods" in reaching his proffered opinion on causation. Pet. App. 10a-13a. The district court's opinion makes clear, however, that it neither placed undue weight on the mere number of a particular type of study (see *id.* at 58a, 61a) nor thought all animal research unreliable (*id.* at 60a-62a). The court discussed the studies specifically cited to it by respondents in opposing summary judgment (see *id.* at 62a), and the court of appeals did not identify any other study providing more substantial support for respondents' position.[12]

Finally, in our view, the district court did not reject the proffered evidence because it drew a "different" conclusion from the evidence than did respondents' experts, but because it concluded that the experts' conclusion was one that could not properly be drawn for purposes of determining the evidentiary issue in this case. See Pet. App. 67a ("[T]he court is not persuaded * * * that the studies support the 'knowledge' the experts purport to have, i.e., that PCBs, 'to a "reasonable degree of medical certainty,"' * * * promote small cell lung cancer in humans."). That is a permissible conclusion under *Daubert*. The court of appeals, on the other hand, appears to have focused, rather uncritically, on the qualifications of respondents' experts and their own assertions that

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[12] The court of appeals impliedly criticized the district court for deciding the admissibility issue without having before it actual copies of most of the studies it discussed. Pet. App. 13a n.9. As the district court noted (*id.* at 59a n.23, 63a n.27), however, it had before it what the parties chose to provide. While the court certainly had the authority to seek more information, it had no obligation to do so.

their methods and opinions were reliable. See. *id.* at 8a-10a & n.8, 11a.

A district court should not base admissibility of expert testimony on whether it thinks that the testimony is probably right or probably wrong. It must, however, exclude such testimony if it concludes that the basis for the expert's opinion is so unclear or inadequate that it is *mere* opinion—however well informed—rather than testimony concerning scientific "knowledge" that will be "helpful," rather than misleading, to the jury under Rule 702. Compare Fed. R. Evid. 403 (balancing probative value and undue prejudice); *Daubert*, 509 U.S. at 589-590, 595.[13] For the reasons we have discussed, we think the district court acted within the appropriate bounds of its "gatekeeping" role under *Daubert*, 509 U.S. at 597, in determining that the "analytical gap" (Pet. App. 67a) between the materials cited by respondents and the expert opinion they proposed to offer the jury on the issue of causation was too large to be bridged by the *ipse dixit* of their experts, no matter how qualified those experts were. Even if reasonable minds might differ on that issue, the district court would not have abused its discretion in reaching one of two permissible conclusions. Its decision therefore should not have been disturbed on appeal.

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[13] As Chief Judge Posner has put it, the district judge must determine whether the evidence proffered is "genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist." *Rosen* v. *Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir.), cert. denied, 117 S. Ct. 73 (1996).

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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No. 96-188

In The

Supreme Court Of The United States

OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION, and
MONSANTO COMPANY,
Petitioners,

v.

ROBERT K. JOINER and KAREN P. JOINER,
Respondents.

On Writ Of Certiorari
To The United States Court of Appeals
For The Eleventh Circuit

MOTION FOR LEAVE TO FILE BRIEF *AMICI CURIAE* AND BRIEF *AMICI CURIAE* OF BRUCE N. AMES, MICHAEL GOUGH, ARTHUR M. LANGER, RODNEY NICHOLS, FREDERICK SEITZ, ARTHUR CANFIELD UPTON AND RICHARD WILSON IN SUPPORT OF PETITIONERS.

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Letters from all parties consenting to the filing of this brief have been filed with the Clerk of this Court.

Pursuant to Supreme Court Rule 37.6, *amici curiae* state that this brief was not prepared, written, funded or produced by any person or entity other than *amici curiae* or their counsel.

MOTION FOR LEAVE TO FILE BRIEF *AMICI CURIAE*

Pursuant to Rule 36 of the Rules of the Supreme Court, Atlantic Legal Foundation ("ALF") moves this Court for leave to file its brief *amicus curiae* (bound with this motion) on behalf of seven distinguished scientists in support of the ruling of the district court below with respect to the admissibility of plaintiffs' experts' scientific evidence.

Amici believe that they can contribute pertinent and helpful discussion to this Court's understanding of this case. Several of the *amici* appeared before this Court as *amici* in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). *Amici* have no axe to grind but rather are interested only in seeing that proper scientific methodology prevails. In that context *amici* will argue that plaintiffs' expert witnesses failed to use proper scientific methodology and analysis and therefore the district court's decision to exclude their evidence as unreliable was correct.

Amici did not seek the consent of the parties in an effort to maintain their neutral posture. *Amici* pray that this Court grant their motion for leave to file the accompanying brief *amici curiae*.

DATED: New York, New York: May 29, 1997

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INTEREST OF *AMICI*

Amici are scientists, scholars, and teachers of science. Some are recipients of distinguished prizes and awards in their fields. The fields of expertise of *amici* include chemistry, biochemistry, physics, medicine, epidemiology and environmental medicine. Some are or were editors and contributors to scientific and other scholarly journals, and are authors of authoritative works in their respective areas of expertise. Most of *amici* are professors at several of the most highly regarded institutions of higher education in the United States, and one is the former president of one of the most prestigious research universities in the world. *Amici* hold other distinctions for achievements in fields of science and academia. *Amici* are authors of numerous articles, studies, monographs and textbooks. Some are frequently called upon to serve on official commissions, review boards, advisory committees and institutes.

Some of the *amici* previously submitted their views on the nature of scientific knowledge and the methods and procedures of science and the interaction between science and jurisprudence in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

Amici have no interest in the outcome of this case or any other "PCB case." They appear solely as individuals, on their own behalf, to inform the Court of their views as to the appropriate criteria for acceptable scientific evidence, and to argue briefly why the District Court was correct in declining to

admit the plaintiffs' experts' testimony into evidence because it was methodologically flawed and scientifically unreliable. Their interest transcends the issues in this case and the positions of any party.

BRUCE N. AMES is Professor of Biochemistry and Molecular Biology at the University of California in Berkeley, California and was chairman of that department from 1983 - 1989. Dr. AMES received his B.A. from Cornell University in 1950 and his Ph.D., with a biochemistry major, from the California Institute of Technology in 1953. He served from 1954-1960 as a biochemist at the National Institutes of Health. Dr. AMES has received a number of awards, including the Charles S. Mott prize from the GM Cancer Research Foundation, the Gold Medal from the American Institute of Chemists, the Society of Toxicology Public Communications Award and the Wadsworth Award, among others. In 1976 he received a Presidential Appointment from the National Cancer Advisory Board. He served on the Consultative Panel on Hazards of Chemical Pesticides, National Research Council, National Academy of Sciences. He served on the President's Biomedical Research Panel. Dr. AMES has received a number of honors and awards, including membership in the American Academy of Arts and Sciences and the National Academy of Sciences and honorary degrees from Tufts University and the University of Bologna. He was elected a Fellow of the Academy of Toxicology Sciences and a Fellow of the American Academy of Microbiology. He has been the author of over 370 scientific publications and was the 23rd most-cited scientist (in all fields) 1973-1984.

MICHAEL GOUGH is the Director of Science and Risk Studies at the CATO Institute in Washington, DC. Dr. Gough received his B.A. degree in biology from Grinnell College in 1961 where he was a George C. Baker National Scholar and his Ph.D. in Biology from Brown University in 1966. He has taught microbiology at Baylor College of Medicine and the State University of New York. He also served as the Manager of the Biological and Behavioral Sciences Program in the Office of Technology Assessment, U.S. Congress. Dr. Gough was elected Fellow of the Society for Risk Analysis in 1996. He has served on a number of scientific panels and committees, including the Dioxin Reassessment Review Committee of the Science Advisory Board of the U.S. Environmental Protection Agency, Chair of the Advisory Committee on the Health-Related Effects of Herbicides, U.S. Department of Veteran Affairs, Consultant to the Science Advisory Board of the Environmental Protection Agency and member of the Agent Orange Advisory Panel and Advisory Panel on Health Effects Studies in Atomic Veterans of the Office of Technology Assessment. Dr. Gough has written numerous papers and articles and given congressional testimony a number of times about subjects ranging from biotechnology, Agent Orange, dioxin and environmental causes of cancer to such specialized topics as pesticide safety.

ARTHUR M. LANGER is the Director of the Environmental Sciences Laboratory of the Institute of Applied Sciences and Professor of Geology at Brooklyn College of the City University of New York. He was Associate Professor in the Center for Polypeptide and Membrane Research at the Mt.

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RODNEY NICHOLS is President and Chief Executive Officer of the New York Academy of Sciences. He has been a member of the Executive Committee of the Carnegie Commission on Science, Technology and Government and was the principal author of the Commission's report "Science and Technology in U.S. International Affairs" (1992). He is a member of the National Academy of Sciences Committee on International Organizations and Programs. He is the chair of the Committee on Science and Technology in Developing Countries of the International Council of Scientific Unions.

FREDERICK SEITZ is President Emeritus of The Rockefeller University, a leading research institution. In addition to an earned Ph.D. in physics, he has been awarded 30 honorary degrees from such institutions as Princeton

University, Northwestern, University of Michigan, Brown, NYU and University of Pennsylvania. He has received numerous awards for his work as a scientist and educator including the National Medal of Science (1973), the Franklin Medal (1965), the Department of Defense Distinguished Service Award (1968), the Nassau Distinguished Service Award (1969) and the American College of Physicians Edward R. Loveland Memorial Award (1983). He served two terms as president of the National Academy of Sciences and has been Chairman of the Board of the Sloan-Kettering Institute for Cancer Research. He has served on numerous government and academic boards, councils and committees, including the President's Science Advisory Committee, the National Cancer Advisory Board, the Naval Research Advisory Committee and the Advisory Council of the Smithsonian Institution. He has been a member of the boards of trustees of numerous universities and is a member of many United States and foreign scientific academies. He is an editor or a member of the editorial board of numerous scientific publications.

ARTHUR CANFIELD UPTON is Clinical Professor of Environmental and Community Medicine, UMDNJ-Robert Wood Johnson Medical School and also Clinical Professor of Radiology, University of New Mexico School of Medicine. Dr. Upton received his B.A. from the University of Michigan in 1944 and his M.D. from the University of Michigan in 1946. Dr. Upton has also served as Chief of Pathology-Physiology Section, Oak Ridge National Laboratory and Chairman of the Department of Pathology at the State University of New York at Stony Brook. He was also a

Director of the National Cancer Institute from 1977-1979. Dr. Upton has written over 300 published articles, books and reports on radiation injury, carcinogenesis, and environmental toxicology. He is, or has been, a member of the Board of Directors of the Society for Experimental Biology and Medicine, the Society for the Study of Comparative Oncology and the International Consortium for Research on the Health Effects of Radiation. He has also been President of the American Association for Cancer Research, the American Society for Experimental Pathology and the Radiation Research Society.

RICHARD WILSON is Mallinckrodt Professor of Physics at Harvard University, Director of the Regional Center for Global Environmental Change at Harvard University, Affiliate of the Center for Science and International Affairs and the Center for Middle Eastern Studies at Harvard University. He is a past Chairman of the Department of Physics at Harvard University, a past chairman and currently a member of the Cyclotron Operating Committee. He is a member of numerous committees and is consultant to numerous government and academic institutions including the Physics Advisory Board of the National Science Foundation, a member of the Breeder Reactor Safety Committee of the Energy Research and Development Administration, a consultant to the Los Alamos, Oakridge and Lawrence Livermore laboratories, chairman of the Visiting Committee on Radiation Medicine, Massachusetts General Hospital and Director of the Sakharov Foundation. He is a fellow or member of the American Physical Society, the American Academy of Arts and Sciences and the Society for

Physical Research (London). He is the author or editor of over 500 articles, book chapters and other works.

SUMMARY OF ARGUMENT

Scientific evidence to be admissible under *Daubert* must be relevant and reliable. The evidence of plaintiffs' experts was not reliable because they failed to follow proper scientific methodology and failed to bridge the analytical gap between their opinions and the particular facts of the case.

ARGUMENT

SCIENTIFIC EVIDENCE MUST BE RELIABLE.

A. *To Be Admissible Under Daubert Scientific Evidence Must Be Reliable*

This case offers the Court an opportunity to illuminate its ground-breaking ruling in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). In *Daubert*, this Court, by examining and applying the Federal Rules of Evidence, articulated a more flexible and sophisticated standard for the admissibility of expert scientific evidence than had theretofore been applied in the federal courts. *See, e.g., Daubert*, 509 U.S. at 588, 589. This Court amplified Rule 702's requirements as follows:

> Faced with a proffer of expert scientific testimony ..., the trial judge must determine at the outset, pursuant to Rule 104(a), whether the

> expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

Daubert, 509 U.S. at 580 (footnotes omitted).

While it is apparent that this Court intended by its decision in *Daubert* to depart from "rigid" and inflexible, almost talismanic, reliance on one criterion to determine admissibility, it is equally clear, we submit, that the thrust of *Daubert* was to recognize the "gatekeeper" role of federal trial judges, empowering them to enforce "limits on the admissibility of purportedly scientific evidence" and to "ensure that any and all scientific testimony or evidence that is admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 592. This Court in *Daubert* emphasized that the primary criteria to be used in determining admissibility are relevance and reliability. That reliability is to be a desideratum of admissibility is made clear, we believe, in the passage in which the Court addressed the concerns of the respondent and some *amici* in *Daubert* that the "abandonment of 'general acceptance' as the exclusive requirement for admission" would result in juries being "confounded by absurd and irrational pseudoscientific assertions," and sought to allay those fears by emphasizing the "conventional devices available to the court in directing a

verdict or granting summary judgment, citing with apparent favor *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 506 U.S. ----, 113 S.Ct. 84, 121 L.Ed.2d 47 (1992) and *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307 (5th Cir. 1989), *modified*, 884 F.2d 166 (CA5 1989), *cert. denied*, 494 U.S. 1046, 110 S.Ct. 1511, 108 L.Ed.2d 646 (1990)[1].

If, as we believe, the most significant lesson of *Daubert* is that it is important to prevent "pseudoscience" from distorting the legal process, then we submit that this case exemplifies a misreading by the Court of Appeals of *Daubert* and a proper application of *Daubert* by the District Court.

B. *The Evidence of Plaintiffs' Scientific Experts Is Not Reliable*

The central issue raised in the case at bar is what standard of review should an appellate court apply in reviewing a trial court's ruling on the admissibility of scientific evidence. We do not intend to comment on that issue other than to conclude that, regardless of what standard is applied, the district court was correct in denying the admissibility of

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[1] In *Daubert* this Court stated,

> Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 ... exercises more control over experts than over lay witnesses.

Daubert at ----, 113 S.Ct. at 2798.

plaintiffs' experts' testimony.

There is, however, an underlying issue, namely whether the evidence proffered by the plaintiffs' scientific experts was reliable. We submit that it was not.

The ultimate question is whether Mr. Joiner's small-cell lung cancer was caused or promoted by his exposure to PCBs.

Plaintiffs' own experts conceded that there are no studies which show that PCBs cause small cell lung cancer in humans. (Teitelbaum deposition at pp. 110-111).

Plaintiffs' experts, however, referred to four epidemiological studies on which they relied despite the fact that none of these studies supports the proposition that Joiner's small cell lung cancer was caused by PCBs.

First, plaintiffs offered "selected quotes" from Bertazzi, et al., Cancer Mortality of Capacitor Manufacturing Workers, 11 Am.J.Indus.Med. 165 (1987). The Bertazzi study concludes, however, that:

> There were apparently no grounds for associating lung cancer deaths (although increased above expectations) and exposure in the plant. The numbers were small, the value of the risk estimate was not statistically significant, and such risk had never been suggested before.

864 F.Supp. at 1324, quoting Bertazzi, et al., "Cancer Mortality of Capacitor Manufacturing Workers," 11 *Am.J.Indus.Med.* 165, 172 (1987).

Plaintiffs also offered selected passages from Judith A. Zack & David C. Musch, "Mortality of PCB Workers at the Monsanto Plant in Sauget, Illinois" (1979), an unpublished study that Monsanto funded. This study was subsequently superseded by a later version which held that "while many of the cancer-specific [standardized mortality ratios] exceed 100, none [is] statistically significant." *Joiner v. General Electric Co.*, 864 F.Supp. 1310, 1325.

Plaintiffs assert that "[a]nother study of interest is a study of PCB exposed workers in a Norwegian cable manufacturing company. A statistically significant excess of deaths from lung cancer was observed. Ten deaths from lung cancer were observed when only 3.9 were expected." (Plaintiffs' Brief below at 13.) That study, however, "never mentions PCBs and does not involve 'PCB-exposed workers.'

The last study Plaintiffs cite is Ikeda, et al., A Cohort Study on Mortality of Yusho Patients--A Preliminary Report, 78 Fukuoko Acta Med. 297 (1987), which Plaintiffs assert was summarized in a publication entitled World Health Organization's International Programme on Chemical Safety, Polychlorinated Biphenyls and Terphenyls 449 (2d Ed.1993). The "Yusho" incident involved Japanese people who were accidentally exposed to toxic substances. The report states that "'[a] statistically significant excess mortality was seen for

malignant neoplasms, cancer of the liver and cancer of the lung, trachea, and bronchi in males.'" (Plaintiffs' Brief below at 13.)

As defendants correctly observed:

> The [Ikeda] report was published in English by Kuratsune, et al., "Analysis of Deaths Seen Among Patients With Yusho--A Preliminary Report," Chemosphere, Vol. 16, Nos. 8/9, pp. 2085-2088 (1987). As indicated by the title, it is a "preliminary report" of an "analysis of deaths," not an epidemiological study. No regression analysis was done and the authors did not control for cigarette smoking, asbestos exposure, or other causes of cancer. Most significant, however, is the fact that, although the deaths were observed in Yusho patients, the authors did not examine if the observed excess risks might be related to the intake of toxic rice oil. Kuratsune, p. 2087. (Defendants' Brief below at 10 [emphasis in original].)

One of plaintiffs' expert witnesses, Dr. Arnold Schecter, acknowledged that the omission regarding toxic rice oil was significant:

> A. ... We have a voluminous data on human response in Yusho and Yuchem to humans exposed to PCBs, dibenzofurans and dioxins.

> Q. Now, in those two incidents, the Yusho and Yuchem, in both of those [incidents], what was the concentration of PCBs, was it a 65 percent concentration, was it 650 parts per million Aroclor or some equivalent?
>
> A. I don't remember what it was. It was PCB and dibenzofuran and dioxin contamination of rice oil which was used to cook food. I don't think anyone can be certain of what the intake was. (Schecter DEP. at 91 [emphasis added].)

Finally, Dr. Daniel Teitelbaum, the other plaintiffs' expert, did not find much significance in the Yusho report:

> Q. ... What, if any, epidemiological studies have you reviewed in reaching your opinion?
>
> A. ....
>
> ... You've got Kuratsune's studies from Japan. You've got a few cases of lung cancer there. They're not very convincing, as the Japanese lifestyle is different. There's--it's, again, suggestive but not convincing. (Teitelbaum DEP. at 89-90.)

The limitations in the Yusho study (e.g., failure to investigate exposure to other potential carcinogens), the fact that the persons studied were exposed to furans

and dioxins, and the fact that one of Plaintiffs' own experts had a low opinion regarding the relevance of the Yusho study together combined to convince the district court that the study has no utility for Plaintiffs' purposes.

The District Court properly rejected the plaintiffs' experts' reading of epidemiology studies. They drew conclusions from results that were not statistically significant, ignoring the scientific tenet that such results are not accepted as convincing because of the high likelihood they arose by chance. The plaintiffs' experts produced no scientifically acceptable evidence that demonstrates increased lung cancer incidence in workers with known, high PCB exposures. They ignored the many published studies of PCBs that have failed to demonstrate a connection between PCB exposures and lung cancers. *See* list of six occupational epidemiological studies cited at pp. 8-10 of Environmental Protection Agency, "PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures", Wash.D.C. U.S.EPA, 1996 [EPA/600/P-96/001F].

The majority of epidemiology study results relevant to the proposition at issue here come from the experience of workers employed in the manufacture of PCB-containing electrical equipment, especially capacitors. These populations show two significant characteristics for the purpose at issue here: the incidence of lung cancer is not significantly greater in them than in the general public and they carry in their blood and fat significantly larger amounts of components of these fluids than do the general public, sometime a hundred times as

much.[2]

To draw reliable inferences from a series of epidemiology studies it is important to consider all relevant study results, weighting each result by its relevance and soundness. It is not scientifically appropriate to cite results of one or two studies that support one's preconceptions.

The Plaintiff's experts point to two experiments that they insist show the cancer causing potential of PCBs. Both experiments involved injecting suckling mice with 100 percent solutions of PCBs. In both experiments, the mice were exposed to an *"initiator,"* a substance that can initiate the sequence of events that lead to cancer. In one experiment, injections of PCBs were made into the peritoneum of the mice; in the other, the injections were made directly into the stomach. Mice in both experiments did not develop small-cell lung cancer, admittedly Mr. Joiner's disease.

Animal studies are much less reliable than human studies or epidemiological studies when seeking to prove that exposure to some substance causes or produces cancer or some other disease in humans. Second, the particular animal studies relied on by plaintiffs' experts were not reliable. Indeed, the experts made telling concessions that undermined the tests' reliability. As the district court noted, plaintiffs' experts conceded that (1) the lung cancer in the mice exposed to PCBs

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[2]The concentration of PCBs in Mr. Joiner's body was less than "background". There is no indication that he was highly exposed. Indeed, there is no evidence that he was more exposed than members of the non-occupationally exposed population.

was not small-cell carcinoma, the type that Mr. Joiner developed; (2) they did not know if the cancer that was detected in immature mice would also be found in mature mice exposed to PCBs; (3) the tumors were dose-related; (4) before being exposed to PCBs, the mice were injected with a known cancer initiating substance and then injected with a 100% solution of PCBs directly into the abdominal cavity or the stomach itself; and (5) the results of the studies were preliminary only. 864 F.Supp. at 1322-24.

Moreover, the fluids to which the plaintiff claims exposure have in fact been tested in more conventional rodent studies. These tests showed no increase in the lung cancer rate. *See,* Environmental Protection Agency, "PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures", Wash.D.C. U.S.EPA, 1996 [EPA/600/P-96/001F], at pp. 10-19

The animal studies plaintiffs' experts relied upon were not indicative of a link between PCB exposure and Joiner's type of cancer because the conditions of the mice (huge doses, direct injection, use of initiator chemicals) were not similar to the nature of Joiner's exposure - his "dose" was far smaller, and plaintiffs' experts have not identified an "initiator". Those tests did not mimic human exposures.

The District Court was correct in rejecting these contrived experiments as evidence that bears on Mr. Joiner's cancer.

Thus, plaintiffs admitted that there were no studies that showed that PCBs caused small-cell lung cancer in humans; referred to several epidemiological studies that were preliminary, equivocal, inconclusive at best and generally reflected no causal relationship between PCBs and Joiner's illness; and relied heavily on two mouse studies which were methodologically flawed and bore no basis in scientific fact to Joiner's exposure to PCBs and his disease.

Plaintiffs' experts failed to bridge the analytical gap between the available data and their conclusion that PCBs cause or promote small-cell lung cancer in humans. Because they failed to bridge that gap the district court correctly refused to admit their testimony.[3] *See, Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360-61 (6th Cir.1992), *cert. denied*, 506 U.S. 826, 113 S.Ct. 84, 121 L.Ed.2d 47 (1992). (Regarding animal studies used to show the cause of birth defects, the court found "[t]he analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue ... is too wide. Under such circumstances, a jury should not be asked to speculate on the issue of causation.").

Amici submit that plaintiffs' experts used flawed methodology. They were very selective in what they based their opinions on and ignored the facts of the case. The mice

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[3]The dissenting judge in the Court of Appeals correctly observed that: "It is incumbent on the proponent of scientific evidence to fill the analytical gap between a proferred study and the particular facts of the case," citing to *Daubert* as support for that proposition.

studies which they primarily relied on (they admitted there were no human studies showing any causal relationship between PCBs and small-cell lung cancer) did not fit the facts of this case.

CONCLUSION

We submit that the District Court acted correctly because the methodology used by the Plaintiffs' experts was not scientific. Plaintiffs' experts failed to show that there is a connection between human exposure to PCBs and lung cancer. They failed to show that there is convincing animal evidence that PCBs can cause lung cancer. They offered no scientific methodology or arguments, buttressed by any reasonable review of the available evidence and data that indicate that Mr. Joiner's disease was associated with his occupational exposures. The method used by the plaintiffs' experts' selection of data favorable to their hypotheses while ignoring the overwhelming information that points away from it is not scientific and therefore the "evidence" upon which it is based is not reliable.

For the reasons stated above, we believe that the Supreme Court should reverse the decision of the Court of Appeals for the Eleventh Circuit and reinstate the decision of the District Court.

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Supreme Court of the United States

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GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
and MONSANTO COMPANY,

Petitioners,

v.

ROBERT K. JOINER and KAREN P. JOINER,

Respondents.

On Writ Of Certiorari
To The United States Court Of Appeals
For The Eleventh Circuit

BRIEF OF *AMICI CURIAE THE NEW ENGLAND JOURNAL OF MEDICINE* AND MARCIA ANGELL, M.D., IN SUPPORT OF NEITHER PETITIONERS NOR RESPONDENTS

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STATEMENT OF INTEREST OF *AMICI CURIAE*

The New England Journal of Medicine (NEJM), which is published by The Massachusetts Medical Society, has been for many years one of the foremost peer-reviewed medical journals. *NEJM* is published in the United States and distributed world-wide to physicians and scientists.

Marcia Angell, M.D., an editor of *NEJM* since 1979 and *NEJM*'s Executive Editor since 1988, is the author of *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case* (1996). As an editor of *NEJM*, Dr. Angell has had 18 years of experience in evaluating the validity of medical and scientific studies submitted to *NEJM*. In *Science on Trial* and elsewhere, Dr. Angell has written extensively concerning the criteria that must be met in order to determine that testimony proffered in a scientific area constitutes knowledge developed through the scientific method. A more detailed statement of Dr. Angell's education and experience is appended after the conclusion of this brief.

Petitioners and respondents have consented in writing to the filing of this brief, and their written consents have been lodged with the Clerk.

SUMMARY OF ARGUMENT

Central to many tort cases is the scientific question: did physical exposure to some substance cause the illness or death of the plaintiff? This Court has charged judges with the obligation of deciding whether or not expert testimony proffered for the purpose of answering the

question of scientific causation constitutes scientific knowledge that should be admitted into evidence. Judges, however, are generally not trained scientists.

In order to determine the admissibility of scientific expert evidence, especially when it is not well established in the scientific community whether exposure to the substance at issue is dangerous, judges should make far greater use of their authority to appoint independent, reputable scientists to assist them in making admissibility decisions. The use of such scientists would significantly increase the likelihood that the scientific evidence presented to juries actually constitutes scientific knowledge and not merely speculations or hypotheses.

ARGUMENT

A. Preliminary Statement.

This brief is submitted on behalf of *NEJM* and Marcia Angell, M.D., who speaks as an individual and as *NEJM*'s executive editor. The purpose of this brief is to comment on what constitutes scientific evidence. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), this Court required federal judges to be gatekeepers for scientific evidence in the courtroom, to review expert testimony on scientific matters and to admit such testimony only when it is both reliable and relevant. Dr. Angell's job at *NEJM* is analogous. She helps decide what medical research studies are admitted into the scientific literature. Although there are thousands of medical journals, and a medical research study that does not get published in

NEJM may be published elsewhere, publication in *NEJM* is widely regarded as an endorsement of quality.

Evaluating medical research is not an easy matter. At *NEJM* it is done by seven full-time physician editors, six part-time physician specialists, three statistical consultants, and one consultant in molecular medicine. In addition, *NEJM* uses thousands of outside peer reviewers who are experts in the subjects under study. Most important, *NEJM's* staff and its reviewers have the salient data from each study being evaluated. See *The Journal's Peer-Review Process*, 321 NEW ENG. J. MED. 837-39 (1989). Even with all this expertise and the data, however, *NEJM* is often not confident of the validity of a study and mistakes are sometimes made that must be corrected later. It is clear, however, that less rigorous and painstaking evaluation would lead to many more mistakes. Courts should be equally committed to separating good from bad science.

This brief discusses (1) the essential features of medical research and describes the way it is evaluated by the scientific community; (2) the differences between the way scientists approach a question of biologic fact and the way courts approach the same question, often with discrepant results; and (3) ways in which the discrepancies in results reached by scientists and courts can be minimized.[1] Amici Curiae do not intend to comment on the particulars of the evidence proffered in *General Electric v.*

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[1] For additional discussion of the topics covered in this brief, *see* MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE (1996).

Joiner. Rather, this case is an example of a type of litigation that underscores the necessity for a better understanding of scientific issues in the courtroom.

B. The Nature of Scientific Evidence.

Central to many tort cases is a scientific question: did physical exposure to some substance cause the illness or death of the plaintiff? For example, in this case, the scientific question is whether exposure to high levels of polychlorinated biphenyls (PCBs) caused Mr. Joiner's lung cancer. In some cases, the question of scientific causation may be relatively easy to answer. For example, where a plaintiff proves he or she ingested food contaminated with *C. botulinum*, and has an injury consistent with such ingestion, there should be no substantive scientific question as to causation since the danger of *C. botulinum* toxin is well established. Substantive scientific questions as to causation primarily arise when it is not well established whether exposure to a substance is or is not dangerous. In these cases, what is at issue is not only whether the exposure occurred, but whether it could cause the harm in question. Unless the question of causation can be affirmatively answered, there can be no consideration of liability.

Since the question of whether PCBs cause lung cancer is a matter of biologic fact, it can be answered only through the scientific method. What is the scientific method? In brief, it means formulating a question that can be answered, designing a study that can answer it, collecting objectively verifiable evidence that will address

the question, and drawing only those conclusions supported by the evidence. The ultimate test of the validity of a conclusion is whether it predicts subsequent events. For example, when a scientist reports the development of a hepatitis vaccine, the ultimate test is whether it prevents hepatitis.

Perhaps the most important hallmark of science is its complete reliance on objectively verifiable evidence. That usually means that something must be counted or measured. The reliance on concrete evidence distinguishes science from all other human endeavors. Medical conclusions are no different from other scientific matters, because the human body is a part of nature.

Whether exposure to PCBs causes lung cancer is an example of a particular type of scientific question that requires a particular kind of evidence to answer. Exposure to high levels of PCBs cannot be the sole cause of lung cancer, even if it plays some role, since people not so exposed also develop lung cancer. And exposure to high levels of PCBs do not invariably cause lung cancer, since most people so exposed remain healthy. Thus, the most that could be true is that PCBs *may contribute* to lung cancer – that is, they might be a "risk factor" (something that increases the *chance* of developing a disease). Whether a risk factor is one of several possible causes of a disease or whether it is merely correlated with a real cause may not be known. For this reason, scientists often say that a risk factor is "associated" with a disease, not that it "causes" it. *See* PHANTOM RISK: SCIENTIFIC INFERENCE AND THE LAW (Kenneth R. Foster, et al. eds.1993).

Risk factors can be strong or weak. For example, cigarette smoking is a strong risk factor for lung cancer. This means that smokers have a very much higher chance of developing lung cancer than nonsmokers. The more they smoke, the greater the risk. In fact, people are extremely unlikely to get lung cancer unless they do smoke. Cigarette smoking is so strong a risk factor for lung cancer that we are justified in saying it "causes" cancer, even though we do not yet know exactly how it does so. In contrast, alcohol may be a weak risk factor for breast cancer. The chances of a drinker getting breast cancer, according to some studies, are slightly higher than the chances of a nondrinker, but abstaining from alcohol is unlikely to confer much protection.

It is difficult to prove that something is a risk factor, unless it is a very strong one. The ideal way, scientifically, to prove that something is a risk factor for a particular disease would be to assemble a large group of very similar people and assign half of them (by random draw) to be exposed to the risk factor and the other half not to be exposed. We would then compare what happens to the two groups. Obviously, we cannot do this with PCBs or any other possible risk factor for cancer. Very few, if any, people would volunteer to be exposed to such risks by random draw.

C. Epidemiologic Studies of Risk Factors.

As a practical matter, observational epidemiologic studies are central to the process of identifying risk

factors for disease.[2] In an observational epidemiologic study, medical researchers do not assign people to be exposed to a potential risk. Instead, researchers observe what happens in those who have chosen to be exposed for their own reasons or who happen to be exposed inadvertently. Then researchers compare the incidence of the disease in these people with the incidence in those who are not exposed. There are several forms of observational epidemiologic studies, but only two are of much value in demonstrating risk factors – cohort studies ("cohort" simply means group) and case-control studies. A cohort study of the possible link between PCBs and lung cancer would start with a group of people who are exposed to high levels of PCBs and a group who are not, none of whom has lung cancer. Researchers would then keep track of the two groups over time to see how many in each group develop lung cancer. If more in the PCB group get lung cancer, it would support (but not prove) the hypothesis that PCBs are a risk factor. Usually the result is expressed as a relative risk, which is the risk in the exposed group divided by the risk in the unexposed group. A relative risk of 1.0 means there is no difference; a relative risk of 2.0 means the exposure doubles the background risk.

In contrast, a case-control study would start with a group of people who already have lung cancer (cases)

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[2] *See* CHARLES H. HENNEKENS & JULIE E. BURING, EPIDEMIOLOGY IN MEDICINE (Sherry L. Mayrent, ed., 1987); Marcia Angell, *The Interpretation of Epidemiological Studies*, 323 NEW ENG. J. MED. 823-25 (1990); Gary Taubes, *Epidemiology Faces Its Limits*, 269 SCIENCE 164-69 (1995).

and a group who do not (controls). After the groups are assembled, the researchers would find out how many people in each group were exposed to PCBs. If a greater percentage of cases than controls had been exposed to high levels of PCBs, it would support (but not prove) the hypothesis that PCBs are a risk factor. In either type of study, the bigger the difference between the two groups, the more likely it would be that PCBs are a risk factor. The most difficult part of epidemiologic studies is making sure the groups are similar to each other in all ways except the possible risk factor (in cohort studies) or the disease (in case-control studies). If they are not, differences may be due to other factors known as "confounding variables."

Cohort and case-control studies each have advantages and disadvantages, but one or the other is necessary to come close to answering the question of whether PCBs are a risk factor for lung cancer. Just finding instances of people exposed to high levels of PCBs who develop lung cancer is not enough to prove a connection because we have to know whether such instances are more common in exposed people than in people who are not so exposed. Lung cancer may well occur in some people exposed to PCBs simply by coincidence.

Nor can we rely on animal studies, since animals may differ from people in their response to PCBs. Other laboratory studies are also unable to answer the question of whether PCBs cause lung cancer. Although laboratory studies are unable to answer the question of whether PCBs cause human lung cancer, they may provide ancillary evidence that an association seen in human epidemiologic studies really represents cause and effect. In

addition, once a link between a risk factor and a disease is established, by epidemiologic studies, animal and other laboratory studies and studies of individual patients may help explain how the connection works. But these studies cannot establish the link in the first place. That must be done by epidemiologic studies.

D. General Causation – A Necessary Proxy for Specific Causation.

Epidemiologic studies yield information about probable risk factors in populations, not in individuals. They provide information about average risks in the average person in the population. In order to determine causation in an individual, one must know whether there are individual differences in susceptibility, and if so, what they are. In most lawsuits involving disputed risk factors, however, we do not know enough to make any determination of individual susceptibility. It is difficult enough to determine whether PCBs contribute to lung cancer in the population at large; we have no way of knowing whether they contributed in a particular person. That is true of most tort cases involving a risk factor. For this reason, it is usually necessary for general causation to serve as a proxy for specific causation. We simply assume that what is true for the population is likely to be true for the plaintiff. If an exposure doubles the risk on average, we assume it doubled the risk for the particular plaintiff. In very few cases do we have enough scientific information to do otherwise.

E. The Scientific Method.

How do epidemiologists find the evidence on which their conclusions are based? First, they need to formulate the question they want to answer and design a study that is capable of answering it. The question is usually framed as a hypothesis. "People exposed to high levels of PCBs are more likely to develop lung cancer than other people" is a hypothesis. (For technical reasons, it is usually framed in the negative – "people exposed to high levels of PCBs are *no* more likely to develop lung cancer than other people" – and the researcher tries to prove the "null hypothesis" wrong.) Although this first step in approaching a scientific question seems obvious and simple, mistakes are often made at this point. If, for example, researchers want to know whether high levels of PCBs increase the risk of lung cancer, they need to choose some suitable measurement of exposure to PCBs, such as a high concentration in body fat, and determine whether it is more common in people with lung cancer than in people without lung cancer, all other factors being equal. Since we know that PCBs are not the only possible cause of lung cancer, it is crucial to make sure that other known causes, such as cigarette smoking, are taken into account.

After the study is designed, researchers must collect data. Collecting data means measuring or counting something. This is the concept that many nonscientists are least comfortable with, because it "reduces everything to numbers." "Everything" cannot be reduced to numbers, but some things can and must be. To reach a conclusion about the physical world, we need numbers because they are often the only way that evidence can be expressed.

What is enumerated depends on the study design. When the data are assembled, they must be analyzed appropriately. Often the analysis consists of comparing one set of data with another set to lead to a logical conclusion. Thus, the number of cigarettes smoked and the concentration of PCBs in body fat in people with lung cancer might be compared with the same quantities in people without lung cancer.

The final step in a research study, after the data are analyzed, is to draw the proper conclusions. Just as the first stage of the study (formulating the question and designing the study) is more difficult than it may at first seem, so is the last stage. Interpreting a study is perilous because of the strong temptation to reach conclusions that are more encompassing than the evidence will support. For example, if a study showed that rats injected with PCBs developed cancer, it would be inaccurate to conclude that PCBs cause cancer in people. That conclusion would go far beyond the evidence. The study did not deal with people, and it did not deal with the same type of exposure. Such a study would be useful only in generating a hypothesis that could be tested in people. Mistakes in drawing conclusions are particularly likely when researchers have strong preconceptions about the question they are studying. The conclusions of a research study must be limited to those – and only those – that follow logically and necessarily from the data.

F. Peer Review and Publication.

In science, the requirement for verifiable evidence must be met, no matter who the researchers are or what

their credentials. Not even Nobel laureates are permitted to base a scientific conclusion on educated speculation. (They can, of course, speculate or hypothesize, but that speculation will not be accepted as evidence unless it is put to the test.) One of the most important protections against unwarranted conclusions is the system of peer review and publication. *See* Arnold S. Relman & Marcia Angell, *How Good Is Peer Review?* 321 NEW ENG. J. MED. 827-29 (1989). Researchers are expected to write up their study in a standardized way, with sections dealing with the methods, results, and conclusions, and submit the paper to a scientific journal. The editors of the journal then send the paper for evaluation by other scientists working in the same field. This process of peer review is the cornerstone of scientific research. (Note that scientists performing peer review evaluate the researchers' study design, technical methods, analysis, and interpretation, not their principles, theories, or hypotheses.)

The reason peer review is so important is that even the most honest researchers cannot be expected to judge their own work dispassionately. They are likely to be enthusiastic about their ideas and, almost by definition, not aware of flaws in the design of their study or the interpretation of their data. The process of interpreting data is seldom clear-cut, and it is easy to be unaware that the data are inadequate to support the conclusions. Without the discipline of organizing and presenting their evidence, and without the criticism and revisions stimulated by the peer-review process, researchers may unconsciously misrepresent their work or exaggerate its importance. *NEJM* seldom publishes a research study that has not undergone substantial revision as a result of the peer

review process. Sometimes the revisions are so extensive that the central conclusion of the study must be reversed.[3]

G. Scientific Uncertainty.

In addition to the reliance on objective evidence collected in properly designed studies, science is also characterized by its tentativeness. This may seem counterintuitive to nonscientists who may think science is "cut-and-dried." But, in fact, good scientists rarely reach absolute conclusions. Particularly in medical research, certainty is extremely hard to attain. Instead, medical researchers almost always speak in terms of probabilities. When researchers do a study comparing two antibiotics to treat pneumonia, for example, they will express their findings in terms of the probability that one is better than the other. When they look at the link between cholesterol and heart disease, they frame their results in terms of risks, not certainties. Very few studies are by themselves definitive. In general, science should not embrace the conclusions of one research study until it has been confirmed by other, independent studies. Even then, the studies taken together merely add to the probability that

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[3] Because of the importance of peer review and publication, *NEJM* and two other journals submitted an amicus brief to the Court in *Daubert*, which proposed that publication in a peer-reviewed journal be a criterion for admitting scientific evidence in the courtroom. *See* Brief for Amici Curiae *New England Journal of Medicine, Journal of the American Medical Association,* and *Annals of Internal Medicine* in Support of Respondent, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) (No. 92-102).

the conclusion is correct, without proving it absolutely. Of course, every aspect of life involves considering probabilities: when we drive to work, for example, we intuitively gauge the probability that an oncoming car will miss us. But scientific research is different in that probability and uncertainty are explicitly considered, measured, and expressed as part of the study. We can rarely absolutely prove a hypothesis, although we can gather enough evidence from enough different studies to make the hypothesis so probable that we can say it is true for all practical purposes.

In reaching a decision about causation, the crucial consideration is the totality of evidence. *See* CHARLES H. HENNEKENS & JULIE E. BURING, EPIDEMIOLOGY IN MEDICINE, ch. 3 (Sherry L. Mayrent, ed., 1987). Each study should be considered as part of a mosaic of information that taken together yields the answer to a scientific question. We are on firmer ground when there are several types of studies of different designs, all pointing in the same direction. If studies reach substantially different conclusions, scientists are very cautious about forming any conclusions at all (except the conclusion that more research is needed). Only when there are many consistent studies, as in the case of cigarette smoking and lung cancer, can we begin to speak of causation. It is very unlikely that any one type of study, let alone a single study in isolation, can prove that PCBs cause lung cancer in humans.

H. Deciding Causation When There is Scientific Uncertainty – The Appropriate "Default" Position.

It is often said that because science progresses slowly and tentatively and a lawsuit must be settled relatively quickly and definitively, we are justified in rushing the answer somewhat in the courtroom. That may be true, but it raises the question of what the "default" position should be when there is insufficient evidence concerning scientific causation. In science, the burden of proof is on those who assert a link between an exposure and a disease. The burden is the same in the courtroom: the plaintiff must show that the exposure was more likely than not the cause of the harm. (In epidemiology, that translates to a relative risk of more than 2.0.) But in some highly publicized tort cases, that burden has apparently been significantly lessened. Instead of having to show the likelihood that the exposure caused the harm, plaintiffs have only had to show that it *might* have done so. *See, e.g., Hopkins v. Dow Corning Corp.*, 33 F.3d 1116 (9th Cir. 1994), *cert. denied*, 513 U.S. 1082 (1995). Such a result is contrary to the scientific method and would appear to contradict this Court's insistence in *Daubert* that scientific testimony must constitute scientific knowledge. *See Daubert*, 509 U.S. at 590.

I. Methodology and Conclusions – Can They Be Separated?

What does it mean when different studies come to different conclusions about the same scientific question? Sometimes the discrepancy is relatively minor. Such discrepancies are particularly likely when the risk being

studied is either very small or nonexistent, because confounding variables are then more likely to distort the results even in fairly well-designed studies. But good studies should not produce major differences in conclusions about the same question. When they do, it means that something is wrong, since the studies are trying to discover the same fact of nature. That is why any distinction between methodology and conclusions is artificial. In science, methods and conclusions are inseparable. When the conclusions about a scientific fact are substantially different in two studies, there must be a flaw in the methods of at least one of the studies. By methods (sometimes termed methodology), scientists mean the detailed design, conduct, analysis, and interpretation of a study. Sometimes in law, the term is used very broadly to refer to the general type of study (for example, "animal study"), but such usage is too vague to have any meaning in defining reliable evidence. Animal studies can be reliable or unreliable.

J. Defining Evidence in Science and the Law.

The most important feature of scientific research is its dependence on objective evidence. No scientific conclusion can be accepted without evidence. This is perhaps the only feature of science that is absolute. The law also depends on evidence, but the term has a different meaning in the courtroom. The opinion of a properly qualified expert witness is considered to be "evidence." Expert witnesses need not, however, produce objectively verifiable data to buttress their opinions, let alone point to a consistent body of research published in peer-reviewed

scientific journals. In a sense, this is the reverse of the scientific method. In science, objective evidence leads to an opinion; in the courtroom, the opinion of an expert becomes evidence. A court's emphasis on the qualifications of expert witnesses is very different from the standards of science, in which *ad hominem* considerations are minimized. Scientists are trained to look at the strength of the data, not the credentials of the researcher. Indeed, some scientific journals go so far as to hide the names of the researchers from the peer reviewers, so that the peer reviewers will not be influenced in their evaluation by the researchers' credentials. The issue is not who the expert is; it is the strength of the evidence.

Associated with the law's emphasis on the credentials of expert witnesses is a highly individualistic view of science. In the courtroom, the testimony of expert witnesses may be based on their own research, published or unpublished. It is sometimes even suggested that an expert witness did unpublished work in preparation for the trial, that he or she reached different conclusions from other research on the subject, and that these conclusions may be relied upon because of the witness's qualifications. It is highly unlikely that such a witness is testifying to scientific knowledge. First, as has been pointed out, a single study is rarely definitive. Second, peer review and publication are so much a part of good science that any unpublished work should be regarded warily. And finally, expert witnesses, no matter what their credentials, should be commenting on the totality of evidence, which they almost certainly have not generated single-handedly. The best that can be expected from expert witnesses is

that they explain the state of knowledge about their subject, most of which will have arisen from the work of others. They should not be expected, nor is it desirable for them, to report solely on their own research. Science is a highly collaborative enterprise that progresses slowly in a stepwise fashion. Scientists who stand alone are usually wrong. *See* PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM (1991).

K. Bringing Science and the Law Together – Using Court Appointed Experts.

Since science is a matter of evidence, not a matter of opinion or argument, what is crucial in the courtroom is a scholarly evaluation of the totality of the evidence. In *Daubert*, this Court acknowledged that no one is so lofty or expert that his or her educated speculation is enough to establish a scientific fact. The Court also acknowledged that no jury is so wise that it can recognize reliable science solely by hearing a proffered expert's direct testimony and responses to cross-examination. The Court, therefore, affirmed that judges should act as gatekeepers with respect to the admission of scientific evidence.

Often, a judge could better fulfill this gatekeeper function if he or she had help from scientists. Judges should be strongly encouraged to make greater use of their inherent authority under Federal Rule of Evidence 104(a) to appoint experts to help them review for admissibility the expert testimony proffered by the parties. *See, e.g., Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996) (rulings made with the assistance of experts appointed by court under Rule 104(a) to assist in determining admissibility of

expert testimony) and *compare Hopkins v. Dow Corning Corp.*, 33 F.3d 1116. Reputable experts could be recommended to courts by established scientific organizations, such as the National Academy of Sciences or the American Association for the Advancement of Science. These experts, representing neither side, could evaluate the expert testimony and generally interpret for the judge the current scientific knowledge about the matter at hand. In essence, the scientific community, by relying on its usual methods of research, peer review, and publication, would be helping the judge to fulfill his or her required gatekeeper role of screening testimony for reliability and relevance.

CONCLUSION

A scientific question can be answered only through rigorous scientific research. There should not be one standard of science for scientists and another for the courtroom.

Respectfully submitted,

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In 1993, Dr. Angell was elected to the Institute of Medicine of the National Academy of Sciences. She was a member of the Institute's Committee on the Responsible Conduct of Research, and she currently serves on its

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Dr. Angell writes frequently for the *Journal* and other publications on a wide range of topics. She has particular interests in health policy, the ethics of biomedical research, the nature of medical evidence, and care at the end of life. Her book, *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case*, was published in June, 1996, by W.W. Norton & Company.

In its April 21, 1997 issue, *Time Magazine* named Dr. Angell one of the twenty-five "most influential people in America" for 1997.

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IN THE
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GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,

v.

ROBERT K. JOINER, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

What is the standard of appellate review for trial court decisions excluding expert testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)?

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BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

INTEREST OF THE AMICUS CURIAE

Pursuant to Rule 37 of the Rules of this Court, the amicus curiae, Chamber of Commerce of the United States of America (the "Chamber"), submits this brief in support of the petitioners.[1] The Chamber, a nonprofit corporation organized and existing under the laws of the District of Columbia, is the world's largest business federation. It represents the interests of more than three million businesses and organizations of every size, sector and region.

[1] Letters from all parties consenting to the filing of this brief have been filed with the Clerk of this Court. Counsel for a party did not author this brief in whole or in part. No person or entity, other than the amicus curiae, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

Ninety-six percent of the Chamber's members are businesses with less than 100 employees.

The Chamber is filing this brief amicus curiae in support of petitioners because it believes that the "particularly stringent" standard of appellate review adopted by the Eleventh Circuit substantially dilutes and undermines the "gatekeeping" role of the district courts as set forth in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). By substituting the judgment of the appellate court for that of the district court, by seeking to unduly narrow and soften the scope of the trial court's inquiry, and by advocating an unbalanced and result-oriented approach, the decision of the Eleventh Circuit represents a significant setback to the advances made by the judiciary in dealing with scientific issues.

Because American businesses would be critically affected by a weakening of *Daubert* and because the Chamber's members have had significant experience with the application of *Daubert*, the Chamber's views may be of substantial assistance to the Court's consideration of this case.

SUMMARY OF ARGUMENT

Four years ago, in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), this Court firmly lodged with the trial court the responsibility for screening proffered scientific testimony in order to ensure its relevance and reliability. While some skeptics doubted the ability of trial judges to make such determinations, in the four years since *Daubert*, district court judges have proven the pundits wrong, undertaking their responsibilities with care and deliberation, holding Rule 104(a) hearings and conducting other detailed factual inquiries where appropriate, and by and large achieving consistent, responsible and proper results. The Courts of Appeals, for their part, have further strengthened the process by deferring to the decisions of trial judges who are "closer to the action," but only where they have adhered to the *Daubert* framework and made

appropriate inquiries into the basis, reasoning and methodologies on which purported scientific testimony is founded. In this fashion, the courts generally have applied the *Daubert* screening process in a manner that is both fair and efficient for litigants and for the judicial system as a whole.

The approach adopted by the Eleventh Circuit in this case, however, now threatens to undermine these precepts and undercut the "gatekeeping" responsibility of the trial court. More specifically, the Eleventh Circuit, by applying a "particularly stringent" standard of review, wrongly overturned a district court decision to exclude expert testimony and chastised the district court for undertaking precisely the type of careful and diligent review that *Daubert* requires.

The Eleventh Circuit's employment of a "particularly stringent" standard of review was improper and should be reversed because it fails to give due deference to the discretion and judgment of the trial judge, the judicial actor best positioned to make the fact-bound determinations and balance the competing interests mandated by Federal Rules of Evidence 401, 403, 702 and 703. Requiring appellate courts to conduct detailed factual inquiries under the guise of a "hard look" is not only an unreasonable and inefficient allocation of judicial resources, but violates every traditional principle of appellate review. Moreover, by creating a standard of review that scrutinizes decisions to exclude testimony more rigorously than decisions to admit testimony, the Eleventh Circuit skews the evenhanded approach required by the Federal Rules, and ignores the significant costs associated with requiring litigants to face claims or defenses based on nothing more than speculative "scientific" testimony. For all of these reasons, the proper standard of review should remain abuse of discretion, and this standard should be applied in an evenhanded, objective manner, giving equal deference to decisions to exclude and decisions to admit.

The Chamber's purpose in submitting this amicus brief, however, is not so much to focus on the legal principles that overwhelmingly mandate a reversal of the Eleventh Circuit's decision, but rather to bring to bear the practical experience of the many federal courts that have decided cases under *Daubert*. This experience amply illustrates the ability of trial judges to deal with the many faces of scientific testimony, the necessity for appellate courts to defer to the greater fact-finding abilities of the trial courts, and the absence of any compelling rationale for appellate courts to engage in the type of cold record review called for by the Eleventh Circuit.

ARGUMENT

I. ABUSE OF DISCRETION IS THE PROPER STANDARD OF REVIEW BECAUSE TRIAL JUDGES ARE IN A "BETTER POSITION" TO RESOLVE THE FACT-INTENSIVE ISSUES GOVERNING ADMISSIBILITY UNDER *DAUBERT*

It has long been established that decisions concerning the admissibility of evidence—including the admissibility of expert testmony—are confided to the sound discretion of the trial court, and that such decisions are not to be upset absent an abuse of that discretion. Indeed, that has been the law for more than a century. *See, e.g., Congress & Empire Spring Co. v. Edgar*, 99 U.S. 645, 658 (1878); *Old Chief v. United States*, 117 S. Ct. 644, 647 n.1 (1997). The fundamental policies underlying this long-standing precedent remain just as compelling today, particularly in light of the multiplicity of factual inquiries mandated by *Daubert* and the balancing of interests required by the Federal Rules of Evidence.

A. It Is Clear From the Very Nature of the *Daubert* Process That the Trial Court Is the Judicial Actor Best Positioned to Resolve the Various Admissibility Issues

It is well recognized that standards of review depend in large measure on "a determination that, as a matter

of the sound administration of justice, one judicial actor is better positioned than another to decide the issue in question." *Pierce v. Underwood*, 487 U.S. 552, 559-60 (1988). Issues which are strictly legal in nature are to be decided by appellate courts upon *de novo* review because they "are structurally suited to . . . devote their primary attention to legal issues," whereas issues which are primarily factual in nature are best decided by the trial court in "deference to the unchallenged superiority of the district court's factfinding ability." *Salve Regina College v. Russell*, 499 U.S. 225, 232-33 (1991).

Similarly, in cases presenting "mixed questions of law and fact," this Court has generally recognized the institutional advantages of the trial court and favored an abuse of discretion standard where the issues are primarily factual in nature. *See Miller v. Fenton*, 474 U.S. 104, 114 (1985). In the context of Rule 11 sanctions, for example, where trial courts are called upon to make determinations regarding both the factual and legal bases for the pleading, and ultimately to balance competing considerations in order to evaluate the sufficiency of a party's position, this Court rejected the contention that the legal aspects of the district courts' rulings should somehow be separated out for *de novo* review. Instead, the Court held that appellate courts should apply "a unitary abuse-of-discretion standard" to all aspects of the proceeding:

> Rather than mandating an inquiry into purely legal questions . . . the Rule requires a court to consider issues rooted in factual determinations. . . . Familiar with the issues and litigants, the district court is better situated than the court of appeals to marshal the pertinent facts and apply the fact-dependent legal standard mandated by Rule 11.

Cooter & Gell v. Hartmarx Corp., 496 U.S. 384, 401-02 (1990); *see also Koon v. United States*, 116 S. Ct. 2035, 2046-47 (1996) (adopting a unitary abuse of discretion

standard for trial courts' departures from the Federal Sentencing Guidelines because "the district court must make a refined assessment of the many facts bearing on the outcome, informed by its vantage point and day-to-day experience in criminal sentencing").

The need for trial court discretion is especially compelling where courts must apply a general legal framework to multiple factual contexts. As the Court stated in adopting an abuse of discretion standard in the context of attorneys fee awards:

> One of the "good" reasons for conferring discretion on the trial judge is the sheer impracticability of formulating a rule of decision for the matter in issue. Many questions that arise in litigation are not amenable to regulation by rule because they involve multifarious, fleeting, special, narrow facts that utterly resist generalization . . . .

Pierce, 487 U.S. at 559-62 (internal quotations omitted).

One need look no further than the *Daubert* opinion itself to realize that questions concerning the admissibility of scientific testimony present precisely the same type of "multifarious" issues "rooted in factual determinations" that require deference to the trial court. In particular, *Daubert* requires trial judges to make a variety of determinations, including: (1) whether the reasoning and methodology employed by the expert "fit" the particular facts of the case at bar; (2) whether such reasoning and methodology is reliable or "scientifically valid;" (3) whether the facts and data upon which the opinion is based are "of a type reasonably relied upon by experts in the particular field" as required by Rule 703; and (4) whether the probative value of the proffered testimony "is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury" as provided in Rule 403. 509 U.S. at 589-95. At the same time, however, this is a flexible framework that must be molded to the particular circumstances of each case, and in the

end trial courts must exercise their best judgment in determining what factors should be considered in balancing the requirements of the various Rules. Individually and collectively, these are fact-driven trial court functions, requiring intimate familiarity with the case at hand, the reasoning and methodology employed by the experts in that particular case, and the methodologies and techniques generally employed by those in the relevant scientific field.

B. The Practical Experience of Trial Courts Applying *Daubert* Reinforces the Fact-Intensive and Varied Nature of the Inquiry

The experience of the federal courts in the many cases decided since *Daubert* amply demonstrates the overwhelmingly factual nature of the inquiry. District courts routinely review voluminous documentary evidence, including expert reports, affidavits and depositions, scientific literature, studies and other relevant material, and often hold "*Daubert* hearings" to consider live testimony where needed.[2]

1. *The First Inquiry: Relevance or "Fit"*

Relevance or "fit" is almost purely a factual determination, the type of determination which traditionally is

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[2] The evidentiary issues are particularly pronounced in the context of mass tort and class action cases. *See, e.g., In re TMI Litig. Cases Consol. II*, 911 F. Supp. 775, 785-86 (M.D. Pa. 1996) and *In re TMI Litig. Cases Consol. II*, 922 F. Supp. 997, 1000 (M.D. Pa. 1996) (multiple Daubert hearings conducted over the course of twenty days, with testimony, reports and affidavits from more than two dozen experts, as well as voluminous scientific literature and other documentary evidence); *In re Breast Implant Cases*, 942 F. Supp. 958, 959 (E.D.N.Y. & S.D.N.Y. 1996) ("extensive" Daubert hearing held at which court "heard many witnesses" and received into evidence more than 500 "documents and scientific papers"); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1393 (D. Or. 1996) (breast implant case in which court held hearing "which spanned four intense days" and received into evidence voluminous scientific literature and other documentary evidence).

accorded great deference by appellate courts. *United States v. Abel*, 469 U.S. 45, 54 (1984); *see also Weinstein's Federal Evidence* § 401.02[1] (2d ed. Supp. 1997) ("the determination of whether an item of evidence is relevant is . . . a factual issue; relevance does not address issues of law"). Particularly in the context of scientific testimony, " '[f]it' is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Daubert*, 509 U.S. at 591. In practice, therefore, trial courts must look beyond the relevance of an expert's bald conclusions, and instead conduct sufficient factual inquiries to ensure that the expert's underlying "reasoning [and] methodology properly can be applied to the facts in issue." *Id.* at 593.

In *Cavallo v. Star Enterprise*, 892 F. Supp. 756, 759 (E.D. Va. 1995), *aff'd in relevant part*, 100 F.3d 1150 (4th Cir. 1996), for instance, a case involving alleged respiratory injuries from exposure to a spill of aviation fuel, the district court carefully reviewed not only the experts' reports, affidavits and deposition transcripts, but also evidence concerning the nature of the plaintiff's alleged injuries and each of the four studies upon which plaintiff's experts relied. Based on this extensive review of the evidence, the court concluded that "there [was] a lack of 'fit' between the studies relied upon and the conclusion reached" by the experts because the studies involved different chemicals, at different levels of exposure and for substantially longer periods of time than in the case at bar, and because in each study "[n]one of the exposed individuals suffered lasting effects" like the injuries plaintiff claimed. *Id.* at 765-70.

A detailed examination and comparison of the facts of the case and the underlying foundation for the expert's opinions also resulted in a finding of a lack of fit in *Bennett v. PRC Public Sector, Inc.*, 931 F. Supp. 484 (S.D. Tex. 1996). In that case plaintiffs claimed to have developed carpal tunnel syndrome from working

on a computer-aided dispatch system manufactured by defendant. Following a six-hour evidentiary hearing and its consideration of expert affidavits and extensive scientific literature, the trial court entered a series of findings identifying numerous factual omissions in the investigation and analysis conducted by plaintiffs' ergonomics expert, and ultimately concluded that his testimony was "based on such limited information about each of the Plaintiffs individually that there is no 'fit' between Plaintiffs and Dr. Schultze's general theory." *Id.* at 500.[8]

2. *The Second Inquiry: Reliability*

In *Daubert*, the Court set out a nonexclusive list of factors that district courts should consider in assessing reliability, including: (1) whether the expert's theories and methodologies have been, or can be, empirically tested; (2) whether they have been subjected to peer review and publication; (3) their general acceptance in the relevant scientific community; and (4) the potential rate of error. 509 U.S. at 593-94. Each of these factors requires a factual determination based on the relevant evidence, a truism that has been born out by experience.

In *Government of the Virgin Islands v. Penn*, 838 F. Supp. 1054 (D.V.I. 1993), for instance, a criminal case involving the admissibility of DNA test results, the district court, after holding two evidentiary hearings, lis-

[8] *See also, e.g., Haim v. Secretary of the Dep't of Health and Human Servs.*, No. 90-1031V, 1993 WL 346392, at *10-15 (Ct. Cl. Aug. 27, 1993) (holding evidentiary hearing with testimony by experts and treating physicians, reviewing scientific literature and medical records, and determining that expert's conclusion that DPT vaccine caused infant's death was founded on a single study of mice involving substantially higher doses "injected numerous times . . . in places unsuitable for humans, such as directly into the brain"); *Chikovsky v. Ortho Pharm. Corp.*, 832 F. Supp. 341, 343-46 (S.D. Fla. 1993) (reviewing expert affidavits and depositions, and determining that testimony regarding alleged carcinogenic effect of topical acne medication was founded solely on studies involving different medications "taken orally and in much higher doses").

tening to competing witness testimony, reviewing several hundred pages of expert affidavits and considering substantial amounts of scientific literature, methodically considered each of the four *Daubert* factors and entered extensive, corresponding findings of fact. In particular, with respect to the potential rate of error in DNA testing, the court devoted over fifteen pages of its decision to its findings regarding the principles underlying DNA profiling, the procedures followed by the FBI in conducting the DNA tests in that case, and "the means by which the FBI prevents both potential sources of human error in the execution of the process and potential error caused by imperfections inherent in the process." *Id.* at 1057-73.[4]

In *Bradley v. Brown*, 852 F. Supp. 690 (N.D. Ind.), *aff'd*, 42 F.3d 434 (7th Cir. 1994), a case involving allegations that plaintiffs had suffered MCS (multiple chemical sensitivity) as a result of a single exposure to a commercial pesticide, the trial court analyzed the deposition testimony of plaintiffs' two experts and "literally hundreds of pages of material discussing MCS" in order to determine "whether the proffered testimony . . . can be and has been empirically tested." *Id.* at 698-700. Based on its review of the evidence, the trial court found that the experts' testimony had not been tested, but rather was founded on nothing more than "uncontrolled" and unreliable "anecdotal" observations, and that even the scientific literature revealed a consensus that "[p]roper epidemiological research on the characteristics of MCS" was needed. *Id.*[5]

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[4] *See also, e.g., Hein v. Merck & Co.*, 868 F. Supp. 230, 231-34 (M.D. Tenn. 1994) (reviewing expert testimony and scientific literature and assessing the potential for error in hedonic damage expert's methodology); *In re TMI Litig.*, 922 F. Supp. at 1015-19 (reviewing expert testimony and scientific literature and assessing the potential for error in a cancer study conducted for litigation purposes).

[5] *See also, e.g., Schmaltz v. Norfolk & W. Ry.*, 878 F. Supp. 1119, 1121-23 (N.D. Ill. 1995) (reviewing expert affidavits, deposition testimony and scientific literature, and determining that the medical experts have "neither performed nor identified any studies . . . in the scientific or medical literature that links [the herbicide] atrazine . . . to [the alleged respiratory syndrome] RADS"); *Sorensen v. Shaklee Corp.*, Civ. 1-91-CV-70007, 1993 WL 735819, at *2, 6 (S.D. Iowa Sept. 28, 1993) (reviewing expert affidavits, deposition testimony and scientific literature, and determining that medical experts' theory regarding alleged teratological effect of chemically-treated alfalfa tablets "has not been tested, has not been subjected to peer review or publication, and no evidence of its general acceptance has been offered"), *aff'd*, 31 F.3d 638 (8th Cir. 1994).

Similarly, in *Wade-Greaux v. Whitehall Laboratories, Inc.*, 874 F. Supp. 1441, 1448 (D.V.I.), *aff'd*, 46 F.3d 1120 (3d Cir. 1994), a case in which plaintiff claimed to have suffered birth defects as a result of her mother's use of Primatene Mist, the "court conducted a hearing spanning seven separate days," heard testimony from nine expert witnesses, reviewed substantial scientific literature, and entered extensive findings of fact: identifying the relevant scientific field as teratology, describing the methodologies generally employed by teratologists, determining the methodologies used by plaintiff's medical experts in that case, and finally comparing those methodologies to those generally employed by teratologists. *Id.* at 1448-73, 1478. Based on this extensive review of the evidence, the court found numerous, significant departures from accepted methodologies: "Each of plaintiff's expert witnesses is able to draw his or her respective conclusions only by ignoring the basic requirements of the relevant scientific community's methodology." *Id.* at 1478.[6]

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[6] *See also, e.g., Diaz v. Johnson Matthey, Inc.*, 893 F. Supp. 358, 361, 365-77 (D.N.J. 1995) (holding a two and one-half day hearing, reviewing expert reports, deposition transcripts and scientific literature regarding workplace exposure to platinum salts, and entering extensive findings of fact identifying numerous departures from accepted methodologies); *Baxter Healthcare*, 947 F. Supp. at 1402-14 (holding a four-day hearing, reviewing voluminous documentary evidence, and conducting a separate and detailed *Daubert* analysis for each of seven experts on alleged injurious effects of breast im-

Heeding this Court's caution that the *Daubert* analysis is to be a "flexible one" and that "[m]any factors will bear on the inquiry," district courts have also considered a number of other factors, such as: (a) whether the expert opinion was developed solely for litigation, *see Diaz*, 893 F. Supp. at 377 (excluding testimony where expert had never "utilized his diagnostic method other than for purposes of litigation");[7] (b) whether the expert's choice of methodologies was driven by preconceived conclusions, *see Sorensen*, 31 F.3d at 649 (excluding testimony where "[i]nstead of reasoning from known facts to reach a conclusion, the experts here reasoned from an end result in order to hypothesize what needed to be known but what was not");[8] and (c) whether the experts attempted to rule out other potential causes, *see Bennett*, 931 F. Supp. at 492, 499 (excluding testimony where expert "made no meaningful attempt to exclude

plants); *Cavallo*, 892 F. Supp. at 764-71 (reviewing evidence and entering extensive findings identifying and comparing methodologies employed by experts with those generally employed in the field of toxicology, and determining that "while the agreed-upon methodology appears to be scientifically valid, it does not appear to have been faithfully applied" in this particular case).

[7] *See also, e.g., Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1384 (N.D. Cal. 1995) (excluding medical testimony where "opinion was developed for the express purpose of testifying"); *Wade-Greaux*, 874 F. Supp. at 1479 (excluding testimony where expert employed a different methodology in litigation than she did "when addressing her scientific peers"); *Haim*, 1993 WL 346392, at *6, 11 (excluding testimony where expert utilized different practices in litigation than he did in his scientific practice); *but see In re TMI Litig. Cases Consol. II*, 910 F. Supp. 200, 203 (M.D. Pa. 1996) ("That Dr. Kozubov thought that he was performing the study solely for scientific purposes speaks highly of the integrity of the study.").

[8] *See also, e.g., Cavallo*, 892 F. Supp. at 764 n.12 ("It is fairly clear from a review of the record that in many instances, Dr. Monroe did not follow the methodology to form his opinion, but rather formed his opinion and then tried to conform it to the methodology.").

other potential causes of the Plaintiffs' injuries," including "multiple, well-recognized, non-work-related potential causes for [carpal tunnel syndrome]").[9] Each of these additional factors, like the four factors set forth in *Daubert*, is highly factual in nature, focusing specifically on the individual circumstances of the plaintiff and the particular process used by the expert in that case.

3. *The Third Inquiry: Rule 703*

In addition to the relevance and reliability requirements of Rule 702, trial judges must be mindful of the requirements of Rule 703. *Daubert*, 509 U.S. at 595. "In determining whether the expert has based his or her opinion on data of a type reasonably relied on by experts in the field, the courts must evaluate the opinion and its foundation on a case-by-case basis." *Weinstein's Federal Evidence, supra*, § 703.05[2][a].

In *Haim*, for instance, a case involving an infant death allegedly resulting from inoculation by the DPT vaccine, the court determined that the opinion of plaintiff's expert, a pediatric neurologist, was based primarily on a single British study. However, upon careful examination of the study itself, as well as related scientific literature and expert testimony, the trial court found that the study was wholly untrustworthy and not one upon which reasonable scientists would rely to determine causation because the results were statistically insignificant and because the authors of the study themselves "criticized their own design of the study," "recognized that [it] may be biased in the

[9] *See also, e.g., Chikovsky*, 832 F. Supp. at 345 (reviewing extensive evidence and determining that expert had failed to conduct any "genetic studies to determine whether there are genetic explanations for Honey's birth defects"); *Diaz*, 893 F. Supp. at 366, 376 (excluding testimony where plaintiff failed to rule out numerous other potential causes of asthma, including a family history of asthma, a history of smoking and possible exposure to industrial allergens at prior jobs).

selective reporting of children," and conceded "that the [study] has not been replicated by other case-control studies." 1993 WL 346392, at *5-6, *12-13.[10]

4. *The Final Inquiry: Balancing*

In addition to the extensive fact-finding function discussed above, trial courts also must engage in the type of balancing to which appellate courts ordinarily defer. For example, not every case will involve each of the many factors discussed above. One of the more difficult threshold judgments trial courts routinely make is which factors to consider, and of course it is not uncommon for some factors to weigh in favor of exclusion and others to weigh in favor of admissibility. In those cases, judges carefully assess the competing considerations and, based on their experience and judgment, reach a decision not only as to the relevance and reliability of the proffered testimony, but ultimately as to whether it will be helpful to the jury. *See, e.g., In re TMI Litig.*, 911 F. Supp. at 788-826 and 922 F. Supp. at 1019-36 (balancing competing factors for numerous experts). Similarly, it may be that only certain aspects of the challenged testimony are unreliable, in which case district courts again must exercise their judgment in determining which portions of the testi-

[10] *See also, e.g., De Jager Constr., Inc. v. Schleininger*, 938 F. Supp. 446, 450-55 (W.D. Mich. 1996) (holding *Daubert* hearing, and concluding that opinion was not founded on "the type of facts upon which a certified public accountant would rely" and "deliberately ignor[ed] documents and figures which would strike a certified public accountant in the face"); *Casey*, 877 F. Supp. at 1383-86 (reviewing expert affidavits and underlying study, and concluding that opinion was based solely on "case reports [which] are not reliable scientific evidence of causation"); *Henry v. Hess Oil V.I. Corp.*, 163 F.R.D. 237, 247 (D.V.I. 1995) (reviewing expert's trial testimony and other evidence concerning expert's methodology, and concluding that vocational psychologist's testimony "was unreliable and lacked an adequate factual foundation under [Rule 703]").

mony, if any, to admit and which portions to exclude. *See, e.g., Guillory v. Domtar Indus. Inc.*, 95 F.3d 1320, 1330-31 (5th Cir. 1996).[11]

Finally, because "[e]xpert evidence can be both powerful and quite misleading," *Daubert*, 509 U.S. at 595, trial judges routinely balance the competing considerations articulated in Rule 403, particularly where it appears that an expert's testimony is of questionable or marginal relevance or reliability. *See, e.g., De Jager Constr.*, 938 F. Supp. at 453 (concluding that expert's opinion, "has little, if any, probative value" and "would confuse the jury and prejudice [the opposing party]").[12]

Each of these assessments requires an intimate familiarity with the case, and consequently:

> When a balance of this sort has to be struck, it should, except in rare instances, be left to the discretion of the trial judge, subject to review for abuse. It is he who is in the best position to weigh the relevant factors, such as the value of the disputed evidence as compared with other proof adducible to the same end and the effectiveness of limiting instructions.

Eichel v. New York Central R.R., 375 U.S. 253, 256 (1963) (Harlan, J., concurring in part) (citation omitted); *see also Abel*, 469 U.S. at 54 (district court is accorded "wide discretion" under Rule 403).

[11] *See also, e.g., Gier v. Educational Serv. Unit No. 16*, 845 F. Supp. 1342, 1358 (D. Neb. 1994), *aff'd*, 66 F.3d 940 (8th Cir. 1995); *Liu v. Korean Air Lines Co.*, No. 84 Civ. 0690 (PNL), 1993 WL 478343, at *1 (S.D.N.Y. Nov. 16, 1995).

[12] *See also, e.g., Wade-Greaux*, 874 F. Supp. at 1484-85 (weighing testimony and concluding that because experts ignored the question of "human therapeutic dosages . . . opinions from those witnesses that therapeutic dosages of [the drug] are teratogenic would confuse, mislead and overwhelm the jury"); *Bennett*, 931 F. Supp. at 502-03 (where "the probative value of Dr. Schulze's conclusions . . . is eviscerated because the conclusions are untested and based on unreliable information, the probative value of the evidence is heavily outweighed by its prejudicial effect").

C. The Courts of Appeals Are Not Positioned to Second-Guess the District Court's Exercise of Its Gatekeeper Function

All of this experience under *Daubert* demonstrates that applying Rules 401, 403, 702 and 703 requires the type of multifaceted factual determinations that appellate courts are unequipped to make.[13] It is beyond peradventure that the proper institutional forum for resolving such competing "multifarious" considerations is the district court, *Pierce*, 487 U.S. at 562, because "the district court is better situated than the courts of appeals to marshal the pertinent facts and apply the fact-dependent legal standard[s]," *Cooter*, 496 U.S. at 402. Indeed, "[t]he trial judge's major role is the determination of fact, and with experience in fulfilling that role comes expertise." *Anderson v. City of Bessemer*, 470 U.S. 564, 574 (1985). Trial courts also have vastly more experience dealing with questions of expert testimony. *Compare Koon*, 116 S. Ct. at 2039 ("District courts have an institutional advantage over appellate courts . . . given that they see so many more Guideline cases").[14] By contrast, appellate courts

[13] According to the Third Circuit, "evaluating the reliability of scientific methodologies and data does not generally involve assessing the truthfulness of the expert witnesses and thus is often not significantly more difficult on a cold record." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir. 1994). However, this very rationale has been expressly rejected both by the authors of the Federal Rules and by the Supreme Court. *See* FED. R. CIV. P. 52 advisory committee's note (rejecting this precise argument, stating: "To permit courts of appeals to share more actively in the factfinding function would tend to undermine the legitimacy of the district courts in the eyes of litigants, multiply appeals by encouraging appellate retrial of some factual issues, and needlessly reallocate judicial authority."); *Anderson*, 470 U.S. at 574 ("The rationale for deference . . . is not limited to the superiority of the trial judge's position to make determinations of credibility.").

[14] Even courts that lay claim to an appellate gatekeeper role are forced to acknowledge the trial court's "superior vantage point" for the resolution of evidentiary matters and that the trial court's

lack the opportunity, tools, context and experience to engage in the detailed examination that *Daubert* mandates. Not surprisingly, therefore, *Daubert* leaves no doubt that responsibility for this function is lodged squarely in the trial court. *See Daubert*, 509 U.S. at 589 ("under the Rules *the trial judge* must ensure" relevance and reliability) (emphasis added); *id.* at 591 ("*the trial judge* must determine . . . whether the expert is proposing to testify to . . . scientific knowledge that . . . will assist the trier of fact") (emphasis added). The assertion that the appellate courts can assume something like a *de novo* role with respect to the gatekeeper exercise is thus inconsistent with the functional learning derived from the experience of trial courts under the Rules, with the role appellate courts generally play with respect to both fact and evidentiary issues, and with *Daubert*'s clear allocation of gatekeeper responsibility to the trial judge.

Even if the appellate courts were equally positioned to play the gatekeeper role, however, no benefits have been identified to offset the waste of judicial resources that would be involved in allocating scarce appellate resources to a second review of factual determinations. As this Court said in *Pierce*, "even where the district judge's full knowledge of the factual setting can be acquired by the appellate court, that acquisition will often come at unusual expense, requiring the court to undertake the unaccustomed task of reviewing the entire record." 487 U.S. at 560; *see also Anderson*, 470 U.S. at 574 ("Duplication of the trial judge's efforts in the court of appeals would very likely contribute only negligibly to the accuracy of fact determination at a huge cost in diversion of judicial resources.").

The waste of private resources resulting from repetitive considerations of gatekeeper issues also calls into ques-

superior position means that its "evidentiary rulings are generally subject to a particularly high level of deference." *Paoli*, 35 F.3d at 749.

tion the wisdom of a stringent factual review in the court of appeals. Particularly in the context of toxic tort and other complex litigation, a rule that requires parties to prove their case twice in order to exclude unsupported scientific evidence would impose significant and unwarranted costs and burdens on the American business community. One need look no further than the *Paoli* case for such an example. In that case, questions regarding the admissibility of plaintiffs' expert testimony went up to the court of appeals three times over a period of seven years for a "hard look" review, and a total of eleven years elapsed before the case was finally resolved in defendants' favor by a jury.[15] Where "the parties . . . have already been forced to concentrate their energies and resources on persuading the trial judge that their account of the facts is the correct one . . . requiring them to persuade three more judges at the appellate level is requiring too much." *Anderson*, 470 U.S. at 575.

For all of these principled and practical reasons, the admissibility of expert testimony historically has been deemed a factual matter to be reviewed only for abuse of discretion. *See Edgar*, 99 U.S. at 658. Deferential review was the norm even under the *Frye* standard where trial courts determined only whether the scientific testimony was based on generally accepted scientific principles. *See, e.g., United States v. Butt*, 955 F.2d 77, 85 (1st Cir. 1992). Under *Daubert*, the inquiry is dramatically more varied and fact-intensive. *See In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d 1124, 1132 (2d Cir. 1995) ("The *Daubert* Court significantly changed the standards governing the admissibility of scientific evidence by expanding district courts' discretion to evaluate the reliability and relevance of contested evidence."). Thus, the very nature of *Dau-*

[15] *See In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829 (3d Cir. 1990); *Paoli*, 35 F.3d 717 (3d Cir. 1994); and *In re Paoli R.R. Yard PCB Litig.*, No. 95-2098, 1997 WL 239652 (3d Cir. May 12, 1997).

bert and the experience of the district courts in carrying out their gatekeeper function only enhances the claim of the trial court to a standard of deferential review that reflects the primacy of its institutional position with respect to the screening of expert witnesses pursuant to the Federal Rules of Evidence.

II. NEITHER THE RISKS OF TRIAL COURT EXCLUSIONARY ERROR, NOR THE PURPORTED PRESENCE OF A PRESUMPTION IN FAVOR OF ADMISSIBILITY, SUPPORT THE ADOPTION OF A STRINGENT STANDARD OF REVIEW APPLIED SOLELY TO THE EXCLUSION OF EXPERT TESTIMONY

Although the *Daubert* inquiries are by their nature committed to the trial court, the Eleventh and Third Circuits claim that the risk of trial court error in excluding expert evidence, when combined with a presumption in favor of its admissibility, require appellate courts to exercise strict scrutiny of decisions excluding, but not those admitting, expert testimony. Neither argument is compelling and ironically the resulting "hard look" threatens to dilute what has proven to be an effective mechanism to screen scientific evidence.

A. The Record of *Daubert* Decisionmaking Provides No Support for the Claim That Rule 702's Standards Are Either Amorphous or Present A Substantial Risk of District Court Error

Implicit in the few appellate decisions advocating a one-sided stringent review of district court decisions excluding proffered scientific evidence is a misplaced concern about the capacity of the district courts to administer the *Daubert* process fairly and to apply properly the predicate admissibility standards of Rules 702 and 703. *See Paoli*, 35 F.3d at 750 ("because the reliability standard of Rules 702 and 703 is somewhat amorphous, there is a significant risk that district judges will set the threshold

too high").[16] This anxiety about the performance of trial judges is flatly inconsistent with the Supreme Court's own analysis. Indeed, when this Court allocated the *Daubert* review to the trial court, it expressly declared that it was "confident that federal [district] judges possess the capacity to undertake this review." 509 U.S. at 593; *see also Michelson v. United States*, 335 U.S. 469, 488 (1948) (Frankfurter, J., concurring) ("[i]f the United States District Courts are not manned by judges of such qualities, appellate review, no matter how stringent, can do very little to make up for the lack of them").

Similarly, the two circuit courts other than the Eleventh that have explicitly considered the *Paoli* risk analysis have both rejected it as inconsistent with both *Daubert* and their own confidence in the ability of the district court judges to successfully resolve these issues. *See Duffee v. Murray Ohio Mfg. Co.*, 91 F.3d 1410, 1411 (10th Cir. 1996); *Cavallo*, 100 F.3d at 1153-54. Notably, neither the Eleventh Circuit nor the Third identifies a record of district court decisionmaking that reflects a "significant risk" of preclusion of expert witnesses on grounds that are either amorphous or erroneous. In fact, the experience of district courts instead suggests that the review process mandated by *Daubert* has been successful in isolating failures in methodology and reasoning so as to permit evenhanded and straightforward admissibility determinations. As the cases discussed earlier amply demonstrate, the district court record reflects exclusions of evidence based not on fine points of metaphysics, but rather on wholesale failures to test theories or otherwise support them with appropriate studies, to subject them to peer review, to conform out-of-court methodologies with in-court hypotheses, to consider obvious alternative

[16] Even if the reliability standards of Rules 702 and 703 were amorphous as the Third Circuit suggests, that would not justify a one-sided approach since there is an equal risk that amorphous standards will lead to erroneous decisions to admit as to erroneous decisions to exclude.

causes of the asserted injury, or to investigate facts fundamental to the experts' hypotheses.

Similarly, nothing in the appellate case experience supports the fears that the district courts will be undone by the flexible nature of the *Daubert* process or suggests the need for a heightened level of scrutiny. Mimicking the experience in the district courts, the great bulk of *Daubert* decisions on appeal appear to involve wholesale failures of evidentiary support rather than tortured attempts to comply with elusive requirements of admissibility. In these mainstream cases, abuse of discretion has proven to be more than adequate as an engine of review. Some examples are:

> *Guillory*, 95 F.3d at 1331: Affirmed a partial exclusion of testimony by an accident reconstruction expert under an abuse of discretion standard where the expert's opinion "was not based upon the facts in the record but on altered facts and speculation designed to bolster Deere's position."
>
> *Rosado v. Deters*, 5 F.3d 119, 124 (5th Cir. 1993): Affirmed the exclusion of testimony under an abuse of discretion standard where the expert "himself admitted that he could not independently establish the necessary physical and mathematical bases for his opinion."
>
> *United States v. Tellez*, No. 94-10573, 1995 WL 745968, at *4 (9th Cir. Dec. 14, 1995): Affirmed the exclusion of testimony regarding the reliability of eyewitness identification under an abuse of discretion standard where the expert could "not identify any specific study or theory he relied upon to formulate his opinion."
>
> *Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 597 (9th Cir. 1996): Affirmed the exclusion of testimony attributing birth defects to a fertility drug under an abuse of discretion standard where the expert had not "explained how he went about reach-

ing his conclusions [nor] . . . pointed to an objective source demonstrating that his method and premises were generally accepted by . . . a recognized minority of teratologists."

Claar v. Burlington N. R.R., 29 F.3d 499, 502 (9th Cir. 1994): Affirmed exclusion of testimony attributing various ailments to chemical exposure under a manifestly erroneous standard where the experts utterly failed "to explain the reasoning and methods underlying their conclusions."

Porter v. Whitehall Lab., Inc., 9 F.3d 607, 614, 616 (7th Cir. 1993): Affirmed exclusion of testimony where experts "could not point to [any] studies, records or data" supporting their conclusions and "gave opinions unsupported by any method—generally accepted or otherwise." [17]

In the real world of litigation the courts of appeals only occasionally face the more complex problems of determining whether proffered science that has yet to gain acceptance is nevertheless reliable science with evidentiary value that requires it to be admitted under the Federal Rules. Even in such cases, however, the circuit courts have not engaged in second-guessing, but instead have emphasized the importance of the *Daubert* process, expressing confidence that adherence to that process will yield proper results.[18] Moreover, a review of the appellate

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[17] *See also Deimer v. Cincinnati Sub-Zero Prods.*, 58 F.3d 341, 344 (7th Cir. 1995); *Sorensen*, 31 F.3d at 649-50; *Habecker v. Clark Equip. Co.*, 36 F.3d 278, 289-99 (3d Cir. 1994); *American & Foreign Ins. Co. v. General Elec. Co.*, 45 F.3d 135, 139 (6th Cir. 1995). *Compare United States v. Bynum*, 3 F.3d 769, 773 (4th Cir. 1993) (affirming admission of testimony where criteria plainly met), *cert. denied*, 510 U.S. 1132 (1994); *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1384 (4th Cir. 1995); *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1123 (9th Cir. 1994).

[18] *See, e.g., Gier*, 66 F.3d at 944 (affirming decision because "[t]he analysis conducted by the District Court is precisely the type

decisions involving more complex claims still suggests that the *Daubert* process has been successful in isolating deficiencies of logic and methodology that ultimately provided the courts with rather clearcut bases for decision.

In *Bradley v. Brown*, 42 F.3d 434 (7th Cir. 1994), for instance, the court was faced with questions concerning the scientific etiology of MCS, a controversial, multi-symptom disorder of the 1990's that the district court concluded was at such an "early stage of scientific scrutiny," even the plaintiffs' experts admitted that their etiological models were "speculative" and that epidemiological study was needed. *See Bradley*, 852 F. Supp. at 699-700, discussed at page 13, *supra*. Stating that if "the district court adhered to Daubert's parameters, we will not disturb [its] findings unless they are manifestly erroneous," the Seventh Circuit conducted a review of the district court's findings with respect to the patent deficiencies in the experts' methodologies. 42 F.3d at 436-37. Based on this review, the Seventh Circuit concluded that the trial court "more than adequately adhered to the Daubert framework [and] took its gatekeeping function conscientiously . . . . We will thus not replace the district court's careful decision with our own judgment." *Id.* at 438-39.

The Sixth Circuit in *United States v. Bonds*, 12 F.3d 540 (6th Cir. 1993) was equally focused on the quality of the district court's process in its affirmance of a decision to admit expert testimony relating to DNA analysis under an abuse of discretion standard. Examining the "exhaustive findings" of the magistrate judge and the "very thorough overview of the experts' testimony," *id.* at 556,

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of analysis the decision in *Daubert* would appear to contemplate"); *Pedraza v. Jones*, 71 F.3d 194, 197 (5th Cir. 1995) (affirming decision to strike expert affidavit because the "affidavit satisfie[d] none of the indicia of reliability outlined in *Daubert*"); *Government of the Virgin Islands v. Sanes*, 57 F.3d 838, 841 (3d Cir. 1995) (affirming decision because the "district court properly held a *Daubert* hearing in which the nature of [the expert's] testimony was fully considered").

the appellate court reviewed the trial court's findings under each of the four factors and concluded that while the process of DNA testing is still evolving and results may not be wholly accurate, the "results of the DNA testing were clearly derived from tests based on methods and procedures of science and not based merely on speculation, and were supported by sound and cogent reasoning, even if these methods and procedures are not perfected." *Id.* at 565-66.

At the same time, however, the circuit courts have not hesitated to reverse district court decisions for abuse of discretion, particularly where they have strayed from the principled application of the *Daubert* analytical process. *See, e.g., United States v. Hall*, 93 F.3d 1337, 1342-45 (7th Cir. 1996) (reversing as a clear error of law the district court's decision to exclude psychiatric testimony on the defendant's propensity to give false confessions where the district court "fail[ed] to conduct a full Daubert inquiry;" "[t]he judge never mentioned Daubert specifically, and thus he never focused on the individual questions that must be answered."); *Tyus v. Urban Search Management*, 102 F.3d 256, 263 (7th Cir. 1996) (reversing as a clear error of law the district court's decision to exclude a sociologist's testimony regarding patterns of housing discrimination and a psychologist's testimony on racial targeting where "[i]n neither of its rulings on the experts did the court make use of the framework established by *Daubert*").[19]

[19] Even under an abuse of discretion standard, of course, the courts of appeals can correct errors of law and also determinations of fact that are manifestly erroneous. *Wilton v. Seven Falls Co.*, 115 S. Ct. 2137, 2144 (1995). *See, e.g., United States v. Rouse*, 100 F.3d 560, 566-74 (8th Cir. 1996); *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 781-82 (3d Cir. 1996); *United States v. 14.38 Acres of Land*, 80 F.3d 1074, 1077-79 (5th Cir. 1996); *United States v. Shay*, 57 F.3d 126, 132-34 (1st Cir. 1995); *Joy v. Bell Helicopter Textron, Inc.*, 999 F.2d 549, 567-70 (D.C. Cir. 1993); *United States v. Velasquez*, 64 F.3d 844, 848-52 (3d Cir. 1995); *Ambrosini v. Labarraque*, 101 F.3d 129, 135-41 (D.C. Cir. 1996).

There is nothing in the appellate experience that suggests any reason to doubt the capacity of the trial courts to sort through the requirements of reliability and fit embedded in Rule 702. To the contrary, the process established by *Daubert* has generally proven to be an effective checklist facilitating both district court analysis and traditional appellate review that properly focuses on the reasoning and methodology supporting proffered scientific testimony. The implicit attitude of the vast majority of the circuit courts is that explicitly stated by the Tenth Circuit: "Like the Supreme Court we 'are confident that federal judges possess the capacity to undertake this review.' . . . Their decisions, therefore, are properly reviewed under the traditional abuse of discretion standard." *Duffee*, 91 F.3d at 1411 (quoting *Daubert*, 509 U.S. at 593).

B. Stringent One-Way Review Cannot Be Justified by a Presumption of Admissibility of Undifferentiated Expert Testimony

The second basis articulated by the Eleventh and Third Circuits for exercising a stringent review of trial court decisions excluding expert testimony (but not those admitting expert testimony) is their view that "the Federal Rules of Evidence governing expert testimony display a preference for admissibility." *Joiner v. General Elec. Co.*, 78 F.3d 524, 529 (11th Cir. 1996), *cert. granted*, 117 S. Ct. 1243 (1997). This one-sided and result-oriented approach is flatly inconsistent with the Federal Rules of Evidence, prior decisions of this Court and fundamental notions of fairness.

First, skewed standards of review are not an appropriate mechanism for advancing the substantive goals of a court. Rather, "the reviewing attitude that a court of appeals takes toward a district court decision should depend upon 'the respective institutional advantages of trial and appellate courts,' not upon what standard of review will more likely produce a particularly substantive result."

First Options v. Kaplan, 115 S. Ct. 1920, 1926 (1995). Just as the Eleventh Circuit was mistaken in justifying a "specially lenient" standard of review of district court decisions confirming arbitration awards by reference to a federal policy favoring arbitration, *see id.*, so too is it now mistaken in applying a "particularly stringent" standard of review to decisions excluding expert testimony based upon a purported policy favoring scientific evidence.

Second, to the extent the Eleventh Circuit is equating the liberal thrust of the Rules with a preference for admissibility, it overlooks the fact that the liberal policies underlying the Rules have already been incorporated in the language governing admissibility. That language plainly does not reflect a preference or presumption in favor of irrelevant, unreliable or misleading scientific testimony. To the contrary, "the Rules of Evidence—especially Rule 702 . . . [require] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597; *see also* FED. R. EVID. 402 (expressly stating that "[e]vidence which is not relevant is not admissible," and even relevant evidence is only admissible "except as otherwise provided . . . by these rules"). Indeed, no piece of evidence, and particularly not expert testimony, comes to the table with some predetermined presumption of admissibility. *Compare, e.g.*, FED. R. EVID. 401, advisory committee note ("[r]elevancy is not an inherent characteristic of any item of evidence"). Rather, all evidence begins with an assumption of non-admissibility, and it is the proponent of the evidence who bears the burden of establishing "by a preponderance of proof" that the admissibility standards of the Rules have been satisfied. *Daubert*, 509 U.S. at 593 n.10. In short, there is no preference for admissibility that somehow overrides the express requirements of the Rules, liberal as they may be.

Moreover, these Rules reflect a thoughtful balance on the part of their drafters between the benefits of expert testimony and the dangers inherent in the admission of

junk science masquerading in the costume of scientific expertise, a balance which this Court was careful to preserve in *Daubert* even while recognizing the liberal policies underlying the Rules. *See Daubert*, 509 U.S. at 595 (because "[e]xpert evidence can be both powerful and quite misleading," a trial judge "exercises more control over experts than over lay witnesses"). Thus, while the general acceptance standard of *Frye* was found incompatible with the "liberal thrust" embodied in the Rules, the *Daubert* Court did not replace that standard with an undifferentiated preference for the admission of scientific testimony, but rather with a process designed to test proffered evidence against the requisite standards of reliability and relevance. Contrary to the Eleventh Circuit, what *Daubert* added was not a bias in favor of admission but an unweighted procedure for testing evidence against fair and objective criteria.

The Eleventh Circuit now attempts to add a "preference" on top of the liberal standards already incorporated in the Rules and expressly taken into account by the Court in constructing the *Daubert* framework. Creating a new standard of appellate review based upon such a "preference" would triple-count the "liberal thrust" of the Rules, and stack the deck so heavily in favor of the admission of scientific evidence as to distort the balance struck by the Rules and undermine the requirements of relevance and reliability that alone exclude junk science.

In fact, the decision of the Eleventh Circuit in this case drives home the inevitable reality that if the process is to be driven at every turn by a bias in favor of the undifferentiated admission of expert testimony, it will invite a complimentary appellate review that discourages by form and substance an effective gatekeeper function. The core of *Daubert* is its requirement for an intensive analysis of both the methodology and the reasoning underlying the expert's opinion. Unaccountably, however, the Eleventh Circuit chastises the trial court for precisely this effort

and instead urges an undifferentiated approach that substitutes some generalized notion of cumulative impact for the strict requirement of scientific and logical process.[20] In a sentence that threatens to vitiate the empirical core of *Daubert*, the Eleventh Circuit instructs: "Opinions of any kind are derived from individual pieces of evidence, each of which by itself might not be conclusive, but when viewed in their entirety are the building blocks of a perfectly reliable conclusion, one reliable enough to be submitted to the jury." 78 F.3d at 532. This remarkable generalization by the Eleventh Circuit fails to appreciate, however, that in a proper *Daubert* analysis the critical question is whether the individual pieces of evidence *have been* linked together in a logical and reliable fashion. *See Daubert*, 509 U.S. at 591 (requiring "creditable grounds supporting such a link" in scientific logic). The *Joiner* dissent focuses squarely on the fundamental conflict between this broad-brush approach, that is virtually inevitable in appellate *de novo* review of enormously complex fact-bound determinations, and the necessity for a detailed process that alone will separate real from apparent science: "The majority admonishes the trial court for not 'viewing the bases of the expert's opinion as a whole.' However sifting through the expert's testimony is a crucial 'gatekeeping' function . . . . [A]n expert may not bombard the court with innumerable studies and then, with blue smoke and sleight of hand, leap to the conclusion." 78 F.3d at 537.[21]

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[20] While it discouraged the district court from its detailed analysis, the Eleventh Circuit conducted its own independent review of the record, picking up facts that had not even been briefed by the plaintiff, and then substituted its own judgment about the relevance and reliability of the expert testimony. *Compare Anderson*, 470 U.S. at 576 ("In detecting clear error in the District Court's finding . . . the Fourth Circuit improperly conducted what amounted to a de novo weighing of the evidence in the record.").

[21] It would be naive to believe that the imposition of strict scrutiny for the preclusion of experts would not have an adverse impact on the intensity with which district courts perform their gatekeeper function. District courts have little incentive to perform a time consuming and painstaking analysis with the certain knowledge that they will be second-guessed every step of the way by an appellate court operating on a cold record.

Finally, a stringent standard of review driven by a preference for admissibility undercuts the evenhanded administration of the law, and ignores the enormous risks and costs associated with requiring litigants to face claims and defenses based on nothing more than speculative scientific testimony. While the Eleventh and Third Circuits would strictly scrutinize exclusionary decisions that result in summary judgment, they would not carefully scrutinize decisions to admit scientific testimony no matter how devastating the repercussions may be for individual reputation, commercial interests, or in some instances the loss of liberty itself.[22] All evidentiary decisions involving expert testimony may bear on the ultimate viability of the claims at issue and are significant to one party or the other, and trial judges treat them as such. The significance of these decisions only emphasizes the propriety of a standard of review that respects the indisputably superior position of the trial court to make those determinations. *Compare Salem v. United States Lines Co.*, 370 U.S. 31, 35-37 (1962) (reversing court of appeals for failure to give deference to district court decision to *exclude* expert testimony). Neither case law nor policy support a process of appellate review that weakens rather than strengthens the gatekeeper's commitment to the detailed evenhanded procedures which alone will fairly separate scientific wheat from pseudo scientific chaff.

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[22] *See, e.g., Borawick v. Shay*, 842 F. Supp. 1501, 1501-03, 1507-08 (D. Conn. 1994), *aff'd*, 68 F.3d 597 (2d Cir. 1995); *Sanes*, 57 F.3d at 341.

CONCLUSION

Because the District Court did not abuse its discretion, the judgment of the Court of Appeals should be reversed.

Respectfully submitted,

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In the

Supreme Court of the United States

OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
AND MONSANTO COMPANY, *Petitioners*,

v.

ROBERT K. JOINER AND KAREN P. JOINER,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF THE DOW CHEMICAL COMPANY AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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26 pp

QUESTION PRESENTED

What is the standard of appellate review for trial court decisions excluding expert testimony under *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)?

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No. 96-188

In the Supreme Court of the United States

OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
AND MONSANTO COMPANY,
Petitioners,

v.

ROBERT K. JOINER AND KAREN P. JOINER,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF THE DOW CHEMICAL COMPANY AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

INTEREST OF THE AMICUS CURIAE[1]

Amicus The Dow Chemical Company ("Dow Chemical"), a Fortune 500 company, is a leading manufacturer of plastics, pesticides, herbicides, chlorinated materials, and consumer products, including ZIPLOC™, STYROFOAM™, and SARAN WRAP™. Over the past few decades, chemical manufacturers like Dow Chemical have experienced a

[1] Pursuant to Rule 37.3 of the Rules of this Court, the parties have consented to the filing of this brief. The parties' letters of consent have been filed with the clerk of the Court.

marked increase in the volume of toxic tort litigation. And, alongside this explosion in tort litigation has arisen a substantial growth in the use of expert witnesses to propound theories that purport to demonstrate that a particular substance causes harm to those exposed to that substance. Because these experts are paid by the parties to present their theories to lay jurors, many courts have emphasized the need to be especially vigilant in considering the admissibility of their testimony. This Court's landmark opinion in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), addressed this very issue and clarified the trial courts' role as a "gatekeeper," ensuring that the evidence submitted to the jury in a toxic tort case properly reflects valid scientific methodology and reasoning. Dow Chemical has a significant interest in the federal courts' continued adherence to their responsibilities as set forth in *Daubert*.

One prominent illustration of the need for careful screening of expert testimony in cases involving complex issues of science is the breast implant litigation. Thousands of lawsuits have been filed against Dow Chemical and its subsidiary, Dow Corning Corporation, alleging that breast implants manufactured by Dow Corning cause disease. Whether breast implants do, in fact, cause disease is a question that can be answered only by science. In resolving this question in the litigation context, *Daubert* established essential analytical tools that permit federal courts to ensure that theories of causation are genuine science, not illegitimate speculation. For example, late last year, after holding extensive *Daubert* hearings and taking testimony from neutral, court-appointed experts, a federal district judge in Oregon excluded all of plaintiffs' systemic disease causation experts in a recent breast implant case. *Hall* v. *Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996). Still, thousands of lawsuits remain pending against Dow Chemical. Should these lawsuits proceed to trial, it is vitally important to Dow Chemical that courts of appeals, in reviewing rulings

by trial courts on the admissibility of scientific evidence, are faithful to the fundamental principles established by this Court in *Daubert*.

SUMMARY OF ARGUMENT

I. Although the clear majority of courts of appeals are in general agreement as to the standard of review of district court rulings on the admissibility of proposed expert scientific testimony, two circuits — the Eleventh in this case and the Third — have adopted a contrary position that requires a more stringent, "hard look" examination of district court decisions that *exclude* (but not those that admit) such testimony. While the Third Circuit invokes this standard only when the district court's evidentiary rulings directly result in judgment for the defendant, the Eleventh Circuit appears to apply heightened scrutiny to all decisions excluding expert scientific testimony.

The court of appeals' application of a bifurcated, result-oriented standard of review is contrary to this Court's recent holding that "the reviewing attitude that a court of appeals takes toward a district court decision should depend upon 'the respective institutional advantages of trial and appellate courts,' *not upon what standard of review will more likely produce a particular substantive result.*" *First Options* v. *Kaplan*, 115 S. Ct. 1920, 1926 (1995) (emphasis added) (citing *Salve Regina College* v. *Russell*, 499 U.S. 225, 231-233 (1991)). In the context of ruling on the admissibility of proposed expert scientific testimony, the relative "institutional advantages of trial and appellate courts" — and, hence, the applicable standard of review — do not depend in any way on the results of the trial court's analysis. The basic approach of the district judge applying this Court's decision in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), is the same whether the court ultimately excludes or admits the testimony.

As it did in *Kaplan*, this Court should reject the court of appeals' attempt to adopt a "special" outcome-driven standard of review for a supposedly disfavored class of district court rulings that exclude expert testimony that fails to satisfy the reliability and relevance standards of the Federal Rules of Evidence.

II. The court of appeals' "hard look" review of district court decisions excluding expert scientific evidence reflects a fundamental misunderstanding of the Federal Rules of Evidence and this Court's opinion in *Daubert*. The "liberal thrust" of the Rules replaced many of the "rigid" aspects of prior evidence law with a new "flexib[ility]" (*Daubert*, 509 U.S. at 594), not a "let-it-all-in" philosophy. Under *Daubert*, the trial judge must exercise a gatekeeping function to "ensure that *any and all* scientific testimony or evidence admitted is not only relevant, but reliable." 509 U.S. at 589 (emphasis added). While it is easier under *Daubert* to present *legitimate* conflicting views to a jury because "general acceptance" no longer is an absolute prerequisite to admissibility, the proponent of the evidence must first establish the legitimacy of the proposed testimony by demonstrating that "the reasoning or methodology underlying the testimony is *scientifically valid*" and "properly can be *applied to the facts in issue*." *Id.* at 592 (emphasis added). In view of these formidable burdens imposed by the Federal Rules of Evidence, the court of appeals' assumption that it should be more skeptical of trial court rulings excluding scientific evidence than of rulings admitting such evidence must be rejected.

III. In undertaking its "hard look" review of the district court's decision to exclude respondents' expert testimony, the court of appeals endorsed an interpretation of *Daubert* and the Federal Rules of Evidence that is erroneous as a matter of law. The court of appeals suggests that this Court's statement that "[t]he focus * * * must be solely on the principles and methodology, not on the conclusions that

they generate" (*Daubert*, 509 U.S. at 595) imposes a rigid compartmentalization according to which the district court must "view[] the bases of an expert's opinion as a whole" (Pet. App. at 13a) and may not examine "[w]hether the conclusions advanced from the stated premises in fact follow." *Id.* at 16a-17a (Birch, J., concurring). These restrictions undermine the rigorous empiricism which, as this Court has noted, "'distinguishes science from other fields of human inquiry'" (*Daubert*, 509 U.S. at 593) and prevent district judges from undertaking the critical inquiry into whether, as a matter of scientific method, the purported bases for an expert's opinion actually support that opinion.

In the absence of a rigorous examination of each step in an expert's analysis, courts and juries would have to rely on the word of hired experts that their opinions constituted "scientific knowledge" and "fit" an issue in the case. It simply is inconceivable that in distinguishing between "principles and methodology" on the one hand, and "conclusions" on the other, this Court abdicated to the expert himself the responsibility for ensuring compliance with the Federal Rules of Evidence. Rather, the district court, in the exercise of its gatekeeping duty, must make a preliminary determination that an expert's proposed opinion rests on "good grounds" all the way from hypothesis to ultimate conclusion about an issue in the case. This step establishes the trustworthiness of "any and all" opinions that are submitted to the jury. It then becomes the jury's role to choose which of the competing, scientifically-grounded conclusions is the correct one.

By applying a one-sided standard of appellate review that substantially favors admission over exclusion, the court of appeals has upset the "balance struck by the Rules of Evidence * * * for the particularized resolution of legal disputes." *Daubert*, 509 U.S. at 597. This Court should restore *Daubert* to its proper role in keeping bad science out of the federal courts by (i) reiterating that the same standard

of review should apply regardless of the substantive outcome of the district court proceedings, and (ii) reversing the court of appeals' erroneous application of *Daubert* in this case.

ARGUMENT

I. The Standard Of Review Of District Court Decisions On The Admissibility Of Expert Scientific Testimony Should Not Vary Depending On Whether The Testimony Was Admitted Or Excluded.

This Court's opinion in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993), clarified the trial court's "gatekeeping" duty to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." A question left open by the Court at that time, however, was the appropriate standard of appellate review of district court decisions under *Daubert*. *See* Margaret A. Berger, *Evidentiary Framework*, in Federal Judicial Center, MANUAL ON SCIENTIFIC EVIDENCE 53 (1994) ("Although *Daubert* rejects *Frye*, the opinion does not address the issue of the standard of review").

As Petitioners have noted, the clear majority of courts of appeals have accorded trial courts wide discretion in ruling on the admissibility of proposed expert scientific testimony, reviewing such decisions -- whether they result in exclusion or admission of the testimony -- under a "manifestly erroneous" or "abuse of discretion" standard. Pet. 6-10; Reply Br. 4. Only two circuits, the Eleventh and Third, have adopted a contrary position. See Pet. App. 1a-30a; *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717 (3d Cir. 1994). The standard followed in those two circuits is anomalous in two respects: (1) it entails a more stringent, "hard look" examination of the district court's rulings, and (2) it applies greater scrutiny only to rulings that *exclude* proposed expert scientific testimony.

As one federal judge wrote soon after the Third Circuit first adopted "hard look" review of district court decisions

excluding expert scientific testimony, this novel standard "appears to be without authority or precedent." Thomas A. Wiseman, Jr., *Judging the Expert*, 55 Ohio St. L.J. 1105, 1112 (1994). The Eleventh Circuit appears to have gone further even than the Third Circuit in extending the reach of this bifurcated, result-oriented standard of review. The Third Circuit invokes this heightened standard only when "the district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment." *Paoli R.R. Yard*, 35 F.3d at 750. The Eleventh Circuit, on the other hand, appears to apply "hard look" review to all decisions excluding expert testimony, regardless of whether summary or directed judgment follows directly from the trial court's evidentiary rulings. See Pet. App. 4a-5a.

Perhaps the most compelling reason that the other courts of appeals have declined to follow the lead of the Third and Eleventh Circuits is this Court's admonition that standards of appellate review should *not* be governed by the result of the proceedings in the district court. As the Court observed in *Salve Regina College* v. *Russell*, 499 U.S. 225, 233 (1991), the appellate standard of review is a neutral device designed to reflect "the respective institutional advantages of trial and appellate courts," not an outcome-driven means of promoting substantive policies. In the context of rulings on the admissibility of scientific evidence, the questions that arise in the district court involve both law and fact, and the "institutional advantages" implicated depend to a large degree upon the circumstances. For present purposes, however, the more salient point is that the basic inquiries undertaken by the district court in faithfully applying *Daubert* (and its progeny) to the specific, fact-laden testimony offered in a given case are identical whether the court ultimately excludes or admits the testimony. Thus, the relative "institutional advantages of trial and appellate courts" in addressing the evidentiary questions posed by *Daubert*, and therefore the standard of

review required, do not depend in any way upon the results of the trial court's *Daubert* analysis.

Moreover, even if the Eleventh Circuit were correct in assuming that there is a policy "preference for admissibility" (Pet. App. 4a) of scientific testimony (which, as we show below, is not the case), there is no legitimate ground for changing the appellate standard of review to advance that policy preference. Indeed, in a recent case, *First Options, Inc.* v. *Kaplan*, 115 S. Ct. 1920, 1926 (1995), this Court expressly disapproved a similar effort by the Eleventh Circuit to adopt a bifurcated standard of review that reflected the court of appeals' substantive policy views. In *Robbins* v. *Day*, 954 F.2d 679, 682 (11th Cir. 1992), the court held that the "national policy favoring arbitration" "presumes that reviewing courts will confirm arbitration awards" and justifies an especially lenient "abuse of discretion" standard when reviewing district court decisions that confirm arbitration awards. Decisions that set aside such awards, however, "go[] against the presumption" and therefore must be "review[ed] de novo to protect the integrity of the arbitration process." *Ibid.*

As this Court noted in *Kaplan*, no other court of appeals had adopted the Eleventh Circuit's novel approach. 115 S. Ct. at 1926. This Court, too, declined to import substantive policy concerns into the standard of review, holding instead that "the majority of Circuits is right in saying that courts of appeals should apply ordinary, not special, standards when reviewing district court decisions upholding arbitration awards." *Id.* As the Court explained,

> "For one thing, it is undesirable to make the law more complicated by proliferating review standards without good reasons. More importantly, the reviewing attitude that a court of appeals takes toward a district court decision should depend upon 'the respective institutional advantages of trial and appellate courts,' *not upon what standard of review will more likely produce a particular substantive result.*"

Ibid. (emphasis added) (citing *Salve Regina College*, 499 U.S. at 231-233). The Court further noted that despite the deference owed to agency interpretations under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-844 (1984), "no one, to our knowledge, has suggested that this policy of giving leeway to agencies means that a court of appeals should give extra leeway to a district court decision that upholds an agency." *Kaplan*, 115 S. Ct. at 1926.

In *Kaplan*, this Court unmistakably "put to rest any notion that the standard of review turns upon whether the district court vacated or confirmed the award. In light of *Kaplan*, it is clear that the same standard of appellate review applies regardless of whether the district court confirms or sets aside the arbitration award." *Merrill Lynch, Pierce, Fenner & Smith, Inc.* v. *Jaros*, 70 F.3d 418, 420 (6th Cir. 1995). As it did in *Kaplan*, this Court should set aside an attempt by the Eleventh Circuit to adopt a "special" standard of review for a purportedly disfavored class of district court rulings — namely, those that exclude expert testimony that fails to satisfy the reliability and relevance standards of the Federal Rules of Evidence.

II. The One-Sided Standard Of Review Adopted By The Eleventh Circuit Has No Support In The Federal Rules Of Evidence And Is Contrary To This Court's Teachings In *Daubert*.

Even absent this Court's guidance in *Kaplan*, there would be no justification for upholding a bifurcated, result-oriented standard of review of trial court rulings on the admissibility of scientific evidence. In applying a heightened level of scrutiny to the exclusionary rulings of district courts, the Third and Eleventh Circuits have erroneously concluded that the Federal Rules of Evidence and this Court's opinion

in *Daubert* mandate a global relaxation and liberalization of the admissibility requirements for expert scientific evidence — a mandate which requires appellate courts to be especially wary when trial courts conclude that proposed testimony does not satisfy *Daubert's* requirements of relevance and reliability. As explained below, this approach to the admissibility of scientific evidence mistakenly equates the so-called "liberal" approach of the Federal Rules with a "let-it-all-in" philosophy that cannot be reconciled with this Court's interpretation of the Rules in *Daubert*.

To be sure, *Daubert* did "loosen the strictures of *Frye* and make it easier to present *legitimate* conflicting views of experts for the jury's consideration." Pet. App. 7a (emphasis added). Thus, consistent with its prior observation that the Federal Rules encompass a "general approach of relaxing the traditional barriers to 'opinion' testimony" (*Beech Aircraft Corp.* v. *Rainey*, 488 U.S. 153, 169 (1988)), this Court held that the effect of the "liberal thrust" of the Federal Rules was to replace the "rigid 'general acceptance' requirement" of *Frye* v. *United States*, 293 F. 1013 (D.C. Cir. 1923), with a more "flexible" approach governed by the numerous specific Rules that relate to the admissibility of expert scientific testimony. *Daubert*, 509 U.S. at 594. But the Court's discussion of the rigorous standards for reliability and relevance imposed by several interrelated Rules of Evidence (*id.* at 595) belies the Eleventh Circuit's conclusion that *Daubert* somehow established a "lower threshold" for expert scientific opinions. Pet. App. 8a. As Chief Judge Posner of the Seventh Circuit has written, one part of the *Daubert* opinion held that "the opinion evidence of reputable scientists is admissible in evidence in a federal trial even if the particular methods they used in arriving at their opinion are not yet accepted as canonical in their branch of the scientific community." *Braun* v. *Lorillard, Inc.*, 84 F.3d 230, 234 (7th Cir. 1996). But, Judge Posner continued, "that is only part of the holding of *Daubert*. The other part

is that the district court is responsible for making sure that when scientists testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work." *Ibid.*; *see also* National Academy of Sciences, SCIENCE AND CREATIONISM: A VIEW FROM THE NATIONAL ACADEMY OF SCIENCES 8 (1984) ("Rigor in the testing of hypotheses is the heart of science").

Thus, while the Federal Rules of Evidence relaxed certain outdated limitations on the admissibility of evidence — for example, displacing *Frye*'s rigid requirement that novel scientific evidence gain "general acceptance" in the relevant field as an "absolute prerequisite to admissibility" — they also imposed a gatekeeping responsibility on the district judge, who "must ensure that *any and all* scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 588, 589 (emphasis added). In particular, Rule 104 specifically provides that the district court shall determine "[p]reliminary questions concerning * * * the admissibility of evidence." Rule 702, in turn, establishes the twin prongs of reliability and relevance identified and explained in *Daubert*. And the other rules identified by this Court as bearing on the scientific evidence inquiry — Rules 403, 703, and 706 — also highlight the enhanced preliminary role of the district court under the Federal Rules of Evidence. Applying these Rules as an integrated whole, the district judge must undertake "a preliminary assessment of whether the reasoning or methodology underlying the testimony is *scientifically valid* and of whether that reasoning or methodology properly can be *applied to the facts in issue*." *Daubert*, 509 U.S. at 592-593 (emphasis added).

With these principles in mind, the Eleventh Circuit's notion that the changes brought about by the Federal Rules (as construed by this Court in *Daubert*) mandate a more skeptical review of trial court rulings excluding scientific evidence than of rulings admitting such evidence must be

rejected. While it is true that *Daubert* makes it easier to present *legitimate* conflicting views of experts for the jury's consideration because "general acceptance" no longer is a prerequisite to admissibility, *Daubert* also establishes a rigorous threshold inquiry into whether the proffered testimony is, in fact, legitimate. Indeed, if there is one lesson that the federal courts have learned from *Daubert*, it is that they must demand rigor from the scientists who propose to testify in their courtrooms. See, e.g., *Allen* v. *Pennsylvania Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996) (observing that the goal of *Daubert* "has been to bring more rigorous scientific study into the expression of legal opinions offered in court by scientific and medical professionals"); *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) ("Federal judges ruling on the admissibility of expert scientific testimony face a far more complex and daunting task in a post-*Daubert* world than before"); *Wilson* v. *City of Chicago*, 6 F.3d 1233, 1238-1239 (7th Cir. 1993) (*Daubert* "shifted to the trial judge the responsibility for keeping 'junk science' out of the courtroom"); *In re Joint E. & S. Dists. Asbestos Litig.*, 151 F.R.D. 540, 545 (E. & S.D.N.Y. 1993) (noting that *Daubert* has "broadened and sharpened the trial judge's gatekeeper role to determine whether an expert's testimony both rests on a reliable foundation and is relevant to the task at hand"); see also American College of Trial Lawyers, *Standards and Procedures for Determining the Admissibility of Expert Evidence After Daubert*, 157 F.R.D. 571, 571 (1994) ("*Daubert* clearly requires trial judges to subject expert evidence to more penetrating pretrial scrutiny"); David E. Bernstein, *The Admissibility of Scientific Evidence After Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 15 Cardozo L. Rev. 2139, 2139 (1994) ("most federal courts are interpreting *Daubert* as

giving them wide authority to restrict the scope of admissible scientific evidence in toxic tort litigation").[2]

In sum, far from creating a "lower threshold" for science experts, as the court of appeals erroneously assumed, *Daubert* imposes formidable burdens on experts to demonstrate the reliability and relevance of their theories to the satisfaction of the district court.

III. In Undertaking Its "Hard Look" Review Of The District Court's Decision To Exclude Respondents' Expert Testimony, The Court Of Appeals Improperly Truncated The District Court's Duty Under *Daubert* To Ensure The Reliability And Relevance Of Proffered Expert Scientific Testimony.

In the exercise of its "hard look" review of the district court's exclusion of the respondents' causation experts, the court of appeals in this case reexamined the proffered opinions and the bases cited for them, and concluded that the district court had improperly assessed the admissibility of the testimony. In so doing, the court of appeals endorsed an interpretation of *Daubert* and the Federal Rules of Evidence that is erroneous as a matter of law. The court's flawed application of this Court's teachings results in a watered down application of the district court's gatekeeping responsibilities that severely undercuts the objective of the limitations on the use of expert testimony in the Federal Rules — to "ensur[e] that an expert's testimony both rests on a reliable

---

[2] The trial court's gatekeeping function is even more critical where, as here, the litigation involves an alleged toxic tort. As Judge Weinstein has observed, "[t]he uncertainty of the evidence" in toxic tort cases, "dependent as it is upon speculative scientific hypotheses and epidemiological studies, creates a special need for robust screening of experts." *In re Agent Orange Prods. Liab. Litig.*, 611 F. Supp. 1223, 1260 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987).

foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. It is imperative that this Court not place its imprimatur on the decision or reasoning of the court of appeals below.

At the heart of the dispute between the district court and the court of appeals in this case is the meaning of this Court's statement that "[t]he focus * * * must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. Both the majority and concurring opinions in the court of appeals suggest a rigid compartmentalization of the trial court's review of the proposed expert's "methodology" and his "conclusions." Thus, according to the majority, in conducting its inquiry, the district court must "view[] the bases of an expert's opinion as a whole" (Pet. App. 13a), instead of reviewing "individual studies" or "pieces of evidence." *Id.* at 11a-12a. Or, as Judge Birch observed, determining "[w]hether the conclusions advanced from the stated premises in fact follow" is not part of the district court's gatekeeping role. *Id.* at 16a-17a.

In imposing a rigid distinction between "principles and methodology" on the one hand, and "conclusions" on the other, and on that basis directing district courts to look only to the "bases of an expert's opinion as a whole" (Pet. App. 12a-13a), the court of appeals misapprehended both the nature of science and the rigor with which federal courts must ascertain the "good grounds" for an expert's opinion. Science, as this Court recognized in *Daubert*, "is not an encyclopedic body of knowledge about the universe." 509 U.S. at 590 (quoting Brief for American Association for the Advancement of Science et al. as Amicus Curiae at 7-8). Nor is it simply raw data or bare conclusions. Rather, science "represents a *process* for proposing and refining theoretical explanations about the world that are subject to further testing and refinement." *Ibid.* (emphasis in original). As scientists work to prove (or disprove) various theories, they

build on their own and each others' work in progressing, often one step at a time, from hypothesis to conclusion. While "arguably, there are no certainties in science" (*ibid.*), the rigorous empiricism of the scientific method "'is what distinguishes science from other fields of human inquiry.'" *Id.* at 593.

Unfortunately, the Eleventh Circuit approach undermines this empiricism by preventing trial judges from undertaking a critical inquiry that goes to the essence of what *Daubert* is all about — namely, whether, as a matter of scientific method, the purported bases for an expert's opinion actually support that opinion. By forcing the district court to clump together all of an expert's data (and other bases for his opinion), the court of appeals frustrates any inquiry into whether the expert actually has connected that data to his ultimate conclusions. Indeed, in view of Judge Smith's unassailable observation that "[a] single expert may offer several opinions to reach his ultimate conclusion" (Pet. App. 17a (Smith, J., dissenting)), one wonders precisely how the court of appeals envisions district courts going about the often messy business of "separat[ing] the wheat from the chaff" (*id.* at 22a) while treating the bases of that expert's testimony as an amalgamated whole.

As several courts of appeals have recognized, *Daubert* requires gatekeepers to ascertain that jurors are exposed only to real science, not merely the unsupported conclusions of well-credentialed scientists, when they resolve difficult issues of causation. See, *e.g.*, *Rosen* v. *Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) (Posner, C.J.) ("'an expert who supplies nothing but a bottom line supplies nothing of value to the judicial process'"), *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) (Kozinski, J.) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough."). Close scrutiny of not only the data or underlying bases of expert

scientific opinions, but also the reasoning that connects the data to an issue in the case, prevents clever experts-for-hire from tainting the jury with ultimate conclusions that do not follow from the purported bases for those conclusions. As one respected observer noted,

> "Too often, experts provide only disjointed data wrapped in jargon with no underlying theory or explanation. After listing the facts and studies on which they rely, they simply conclude that according to their medical judgment such an array of information points to causation. * * * Such gobbledygook is not useful or valid science at *any* level of certainty, and should be excluded as inadmissible."

Bert Black, *The Supreme Court's View of Science: Has Daubert Exorcised the Certainty Demon?*, 15 Cardozo L. Rev. 2129, 2132-2133 (1994) (emphasis in original).

Thus, it is not surprising that most courts applying *Daubert* have agreed that the distinction between methodology and conclusions upon which the Eleventh Circuit relied so heavily "has only limited practical import" (*Paoli R.R. Yard*, 35 F.3d at 746), and does not inhibit the district court's duty to sift through the stated bases for an expert's conclusion to confirm that his reasoning is sound (i.e., that it is "scientific knowledge" and that it "fits" the case). See, *e.g.*, *Raynor* v. *Merrell Pharmaceuticals, Inc.*, 104 F.3d 1371, 1374-1375 (D.C. Cir. 1997) (noting that the line between methodology and conclusions "is not all that clear, as propositions may be formulated as conclusions or methodologies with comparatively minor linguistic adjustment"). In the instant case, for example, one of the pivotal questions can be framed as whether it is methodologically sound to draw an inference that PCBs cause small cell lung cancer in humans from (1) testimony based on erroneous assumptions as to exposure and (2) animal studies in the absence of any reliable scientific basis for extrapolating

conclusions based on those studies to humans. Pet. App. 52a-62a.

In assessing whether the expert's conclusions actually follow from the bases upon which the expert purported to rely, it is important to first recognize that the process of generating valid conclusions that form the basis for admissible testimony of a scientific expert frequently involves multiple, reasoned extrapolations from studies or data. See Bernstein, *supra*, 15 Cardozo L. Rev. at 2165-2166. Faithfulness to *Daubert*'s "reliability" prong requires courts to rigorously examine each link in the chain of reasoning or methodology underlying the expert's proposed testimony. As the Third Circuit has explained,

> "*Daubert*'s requirement that the expert testify to scientific knowledge — conclusions supported by good grounds for each step in the analysis — means that *any* step that renders the analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.*"

Paoli R.R. Yard, 35 F.3d at 745 (emphasis in original); see also *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 309-310 (5th Cir. 1989) ("Confronted * * * with difficult medical questions, courts must critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them"). Indeed, the failure to examine the expert's connective reasoning reduces the court (and the jury) to "accept[ing] blindly the expert's word to fill the analytical gap between proffered 'scientific knowledge' and the expert's conclusions." Pet. App. 18a (Smith, J., dissenting).

Rule 702's "helpfulness" or "fit" standard also "requires a valid scientific connection to the pertinent inquiry as a

precondition to admissibility." *Daubert*, 509 U.S. at 591-592; *see also Paoli R.R. Yard*, 35 F.3d at 743 (observing that under "fit" analysis, the "expert's proposed testimony" must be "scientific knowledge for purposes of the case" at bar). In some cases, including this one, an expert may rely on science that is reliable as far as it goes, but nevertheless ought to be excluded on "fit" grounds because "the analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue * * * is too wide." *Conde* v. *Velsicol Chem. Corp.*, 24 F.3d 809, 814 (6th Cir. 1994). As the Third Circuit explained in discussing perhaps the most common "fit" problem:

> "[I]n order for animal studies to be admissible to prove causation in humans, there must be good grounds to extrapolate from animals to humans, just as the methodology of the studies must constitute good grounds to reach conclusions about the animals themselves. Thus, the requirement of reliability, or 'good grounds,' extends to each step in an expert's analysis all the way through the step that connects the work of the expert to the particular case."

Paoli R.R. Yard, 35 F.3d at 743; *see also Barrett* v. *Atlantic Richfield Co.*, 95 F.3d 375, 382 (5th Cir. 1996) ("it is clear that [plaintiff's expert's] testimony could not establish with any scientific reliability whether there was an exposure parallel between the cotton rats and human beings, and we therefore affirm the district court's decision not to admit the testimony"). Thus, for example, even if the use of animal studies in a particular case might be appropriate under Rule 703, the conclusions drawn from specific animal studies about human causation may be unreliable and/or irrelevant under Rule 702 in the absence of valid connective reasoning.

It is true that "a challenge to 'fit' is very close to a challenge to the expert's ultimate conclusion about the particular case." *Paoli R.R. Yard*, 35 F.3d at 746. But the basis for exclusion on "fit" grounds is not the anomalous

nature of the conclusion itself, but rather an error or omission in the expert's connective reasoning that undermines the legitimacy (i.e., the relevance and/or reliability) of the proposed testimony. In many cases, two or more competing opinions will be deemed "scientific," and the court may not invade the province of the jury to decide which conclusion is the correct one. Here, contrary to the court of appeals' view, the district court did not draw any *scientific* conclusions at all, nor did it exclude any of the proffered testimony on the type of "general acceptance" grounds that were relaxed in *Daubert*. Rather, the district court simply examined the foundations for the experts' opinions, the methodologies they followed, and the connective reasoning linking their underlying premises to their ultimate conclusions, and reached the *legal* conclusion that the purportedly "scientific" conclusions propounded by the plaintiffs' experts either were not founded on reliable methodology or were not relevant to issues in the case. This is precisely the type of inquiry envisioned in this Court's opinion in *Daubert*.

* * * * *

As this Court recognized, faithful adherence to the teachings of *Daubert* "inevitably on occasion will prevent the jury from learning of authentic insights and innovations," but nevertheless represents "the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes." *Daubert*, 509 U.S. at 597. In this case, the court of appeals has upset this balance through the operation of a one-sided standard of appellate review that substantively favors admission over exclusion. Furthermore, in applying its "hard look" review, the court undertook no more than a halfhearted examination of an expert's methodology and connective reasoning. This dilution of *Daubert*, if upheld by this Court, raises the specter of self-proclaimed experts evading *Daubert*'s gatekeeping hurdle so long as they are, at some level, performing a scientific endeavor, however

distantly related to any genuine issue in the case. This Court should restore *Daubert* to its proper role in keeping bad science out of the federal courts by (i) reiterating that the same standard of review should apply regardless of the substantive outcome of the district court proceedings, and (ii) reversing the court of appeals' erroneous application of *Daubert* in this case.

CONCLUSION

The judgment of the United States Court of Appeals for the Eleventh Circuit should be reversed.

Respectfully submitted.

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IN THE
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OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
and MONSANTO COMPANY,
Petitioners,

v.

ROBERT K. JOINER and KAREN P. JOINER,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF OF THE AMERICAN MEDICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTIONS PRESENTED

Amicus curiae will address the following questions:

Whether an appellate court should defer to the exercise by a district court of its discretion to exclude proffered expert scientific testimony that did not meet the test of admissibility set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

Whether, in exercising its discretion under Rule 702 of the Federal Rules of Evidence as construed in *Daubert*, the district court may consider the substance of proffered expert testimony to determine whether that testimony has sufficient scientific support to be of assistance to the trier of fact.

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

No. 96-188

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
and MONSANTO COMPANY,
Petitioners,
v.
ROBERT K. JOINER and KAREN P. JOINER,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF THE AMERICAN MEDICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTEREST OF *AMICUS CURIAE*

Amicus American Medical Association (AMA) is a private, voluntary, nonprofit organization of physicians. The AMA was founded in 1847 to promote the science and art of medicine and the improvement of the public health. Its nearly 300,000 members practice in all fields of medicine.

The AMA believes that physicians have an ethical obligation to assist in the administration of justice. This obligation includes the duty to assist in securing a patient's legal rights and in providing relevant and reliable testi-

mony to assist the trier of fact in making decisions. See AMA, *Code of Medical Ethics* § 9.07 (see *infra*, note 5). At the same time, the AMA opposes testimony that (a) is not based on sound scientific or medical research, or (b) is not probative of the point in support of which it is offered. Such testimony serves to prolong meritless litigation and to mislead factfinders. It can have an immediate and lasting impact on the price and availability of physician services, pharmaceuticals, medical devices, and other products.

The AMA is, of course, sympathetic to respondent Joiner for having to endure the ordeal of cancer. As an organization of physicians, the AMA understands full well the awful effects of this horrible disease—both on those whom it afflicts and on their families. But sympathy for the Joiners, and indeed for any sufferer of disease, should not induce courts to make judgments about the cause of disease on the basis of anything less than relevant and reliable scientific evidence.

Reliance by juries on flawed medical or scientific testimony can best be minimized by requiring expert evidence to be methodologically sound, scientifically valid, and properly applicable to the facts of a given case. Expert conclusions based on poor science, or on any science that does not adequately support the conclusion proffered by the testifying expert, should be excluded. Determinations regarding the admissibility of proposed scientific or medical evidence are best made by the trial court, assisted when the court deems it useful, by an independent scientific expert appointed pursuant to Rule 706 of the Federal Rules of Evidence. Decisions excluding expert testimony, like other evidentiary determinations, should be reversed only for abuse of discretion.

The more stringent standard of review adopted by the court below would deter district courts from exercising their gatekeeper responsibilities as articulated by this Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,

509 U.S. 579 (1993). A district court must have discretion to determine whether the scientific evidence relied upon by a proposed expert adequately supports the conclusions to which the expert would testify. Accordingly, *amicus* American Medical Association urges that the judgment of the court of appeals be reversed and that this case be remanded for consideration of whether the district court acted within its discretion in excluding the testimony of respondents' experts.[1]

STATEMENT

Amicus adopts the statement of the case as set forth by petitioners in their brief in this Court and emphasizes the following facts:

1. Respondents relied primarily upon the testimony of two expert witnesses to support their claim that Mr. Joiner's lung cancer, although likely caused by tobacco smoke, was promoted by his workplace exposure to polychlorinated biphenyls (PCBs). Pet. App. 39a. One expert testified that his medical practice focused on persons involved in litigation. J.A. 104, 109, 126-27. The other expert stated that he testifies three to four times per month, "almost always" for the plaintiff. J.A. 167-69.

2. The district court identified several independent grounds for holding that respondents' expert testimony was not admissible to prove causation. Most significantly, the court concluded that respondents' experts lacked an adequate scientific foundation for their conclusion that exposure to PCBs promoted Mr. Joiner's lung cancer.

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[1] Pursuant to Rule 37.6 of the Rules of this Court, *amicus* states that no counsel for a party authored this brief in whole or in part, and that no person or entity other than *amicus* and its counsel made any monetary contribution to the preparation or submission of this brief. Pursuant to Rule 37.3 of the Rules of this Court, the parties have consented to the filing of this brief. The parties' letters of consent have been filed with the Clerk of the Court.

Pet. App. 53a, 59a-62a.[2] In particular, the court held that valid scientific conclusions could not be drawn as to whether occupational exposure to limited concentrations of PCBs could promote lung cancer in humans where the only scientific evidence used to support these conclusions consisted of two studies in which infant mice were injected with high concentrations of PCBs. Pet. App. 59a-62a.

3. The court of appeals identified several factors in concluding that the judgment of the district court failed to withstand what the Eleventh Circuit characterized as the "particularly stringent standard of review" applicable to a trial judge s exclusion of expert testimony. Pet. App. 4a. First, the court of appeals emphasized the fact that respondents' witnesses possessed expert credentials and were familiar with the case. Pet. App. 8a-11a. The court stated that the mere fact of their expertise "augment[ed] the reliability of the reasoning of their methodology." Pet. App. 11a. Second, the court accepted without apparent question the general assertions of these experts that their reasoning conformed to sound scientific practice. Pet. App. 9a-10a. Third, the court of appeals held that, in determining whether an expert's opinion is "legally unreliable," the district court may not consider whether that opinion can validly be drawn from the scientific evidence upon which the expert relies. Pet. App. 11a-13a. Fourth, rather than considering the scientific evidence cited by an expert to support a conclusion, the court held that "the bases of an expert's opinion" must be considered "as a whole" to determine "legal reliability." Pet. App. 13a.

In a special concurrence, Judge Birch emphasized the value of appointing an independent expert, pursuant to Rule 706 of the Federal Rules of Evidence, to assist the court in "evaluating the reliability of the proffered expert

[2] *Amicus* expresses no opinion as to the methodology or validity of any of the studies upon which the experts based their opinions.

evidence." Pet. App. 17a. In dissent, Judge Smith observed that "[i]t is incumbent on the proponent of scientific evidence to fill the analytical gap between a proffered study and the particular facts of the case" and that the trial court "may properly request good grounds to bridge the gap before admitting the testimony." Pet. App. 26a.

SUMMARY OF ARGUMENT

The judgment of the court of appeals should be reversed and the case remanded for that court to determine whether the district court properly exercised its discretion in excluding the testimony of respondents' experts.

I. The court of appeals erred in applying "a stringent standard of review to the trial judge's exclusion of expert testimony." Pet. App. 4a. Determinations regarding the admissibility of evidence in general, and expert testimony in particular, have long rested within the sound discretion of the district court. *Hamling v. United States*, 418 U.S. 87, 108 (1974). Nothing in this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), changed that standard. To the contrary, *Daubert* repeatedly stressed the flexible nature of the inquiry necessary to determine whether expert testimony is grounded in valid science and is properly applicable to the facts of the case. *Id.* at 589, 593, 594 & n.12. "Daubert requires district judges to act as gatekeepers to ensure that scientific evidence is both relevant and reliable . . . . Their decisions, therefore, are properly reviewed under the traditional abuse of discretion standard." *Duffee v. Murray Ohio Mfg. Co.*, 91 F.3d 1410, 1411 (10th Cir. 1996).

II. The substantive criteria applied by the Eleventh Circuit are inconsistent with *Daubert* and would prevent district courts from excluding proffered evidence that is scientifically unreliable or not probative of the question at issue. The court of appeals limited its focus to the general credentials of respondents' witnesses, their asser-

tions that they had adhered to scientific method, and their citation of various studies in support of their opinions. See Pet. App. 10a-13a.

However, to determine whether proffered expert evidence is built on scientifically valid reasoning and methodology that "properly can be applied to the facts in issue," *Daubert*, 509 U.S. at 593, the trial court must examine the substance of the proposed testimony. Specifically, the court must make a preliminary assessment as to whether the research used to support the expert's testimony was conducted in accordance with scientific method and supportive of the expert's conclusion. The district court must consider whether the conclusions to which the expert would testify can, as a matter of good science, be drawn from scientifically-generated data. See Fed. R. Evid. 703. Unsound science and unfounded speculation by scientists should not be admitted into evidence. Such speculation will not "assist the trier of fact." Fed. R. Evid. 702.

III. Allowing district courts to consider the substance of proffered expert testimony in applying the *Daubert* criteria will not, as the court of appeals feared, "turn judges into jurors or surrogate scientists." Pet. App. 7a. A district court may not choose between competing theories when both have sound scientific support. Nor may the court exclude a scientifically supported theory that has yet to achieve widespread acceptance in the scientific community. *Daubert*, 509 U.S. at 594.

It is nevertheless the responsibility of the court to distinguish between subjects of legitimate scientific disagreement on one hand and invalid science on the other. The proper way to discharge this responsibility is to examine the substance of an expert's evidence to determine whether it is (a) predicated on scientifically valid reasoning and methodology and (b) properly applied to the facts at issue. Adequate resources are available to assist judges in making these determinations. Most significantly,

Rule 706 of the Federal Rules of Evidence authorizes the appointment of independent experts to assist the court —an option that district courts should exercise with greater frequency.

IV. Giving trial courts the latitude to consider the substance of an expert's testimony also serves important policy objectives. Legal judgments based upon expert opinions not developed in accordance with scientific methodology have caused manufacturers to withdraw from the market a number of drugs and devices found by the Food and Drug Administration to be safe and effective. Such legal judgments also have stymied innovation in pharmaceutical and vaccine research and caused physicians to discontinue providing certain services. The withdrawal of beneficial products and medical services has a serious and entirely unwarranted adverse effect on public health. Allowing district courts to exclude unsound scientific testimony will promote the factfinding function of the legal process and simultaneously avoid doing violence to the values that undergird science.

ARGUMENT

I. DISTRICT COURT DECISIONS EXCLUDING EXPERT TESTIMONY, LIKE OTHER EVIDENTIARY RULINGS, SHOULD BE REVERSED ONLY IF THE DISTRICT COURT ABUSED ITS DISCRETION.

This Court has repeatedly stated that "the District Court has wide discretion in its determination to admit and exclude evidence, and this is particularly true of expert testimony." *Hamling v. United States*, 418 U.S. 87, 108 (1974). See *Stillwell & Bierce Mfg. Co. v. Phelps*, 130 U.S. 520, 527 (1889). Accordingly, district court decisions admitting or excluding expert testimony have been reviewed with deference. See *Raynor v. Merrell Pharm. Inc.*, 104 F.3d 1371, 1374 (D.C. Cir. 1997); *Duffee*, 91 F.3d at 1411; *Diemer v. Cincinnati Sub-Zero Prods., Inc.*, 58 F.3d 341, 344 (7th Cir. 1995); *United States v. Dorsey*, 45 F.3d 809, 813-14 (4th Cir.), *cert. denied*, 115 S.

Ct. 2631 (1995); *United States v. Sepulveda*, 15 F.3d 1161, 1183 (1st Cir. 1993), *cert. denied*, 512 U.S. 1223 (1994).

Nothing in the language of Rule 702 of the Federal Rules of Evidence indicates an intention to depart from this well-established principle of common law. See generally *United States v. Abel*, 469 U.S. 45, 50-51 (1984) (considering common law in interpreting the Rules of Evidence where the common law precept is consistent with the Rules), *quoted in Daubert*, 509 U.S. at 587-88. The Rule makes no reference to appellate review standards and imposes no specific limitation on the authority of the trial court. It simply provides that an expert may testify "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue . . . ." Fed. R. Evid. 702.

Similarly, nothing in the *Daubert* opinion indicates an intention to apply a heightened standard of appellate review to decisions concerning the admissibility of expert testimony. To the contrary, *Daubert* emphasizes the relationship between Rule 702 and other Rules of Evidence, including Rules 403 and 703. See 509 U.S. at 595. Decisions under these rules are reversed only for an abuse of discretion. See, *e.g.*, *Abel*, 469 U.S. at 54 (Rule 403); *Cummins v. Lyle Indus.*, 93 F.3d 362, 371 (7th Cir. 1996) (Rule 703).[3]

[3] The court of appeals' justification for its "particularly stringent" standard of review lacks merit. Pet. App. 4a. The Eleventh Circuit believed that a heightened standard of review is required because "the Federal Rules of Evidence governing expert testimony display a preference for admissibility . . . ." Pet. App. 4a. In fact, the Federal Rules do not display such a preference. Rather, Rule 402 states a preference for admissibility of "relevant evidence." A preference for admissibility of relevant evidence does not bespeak a heightened standard of appellate review. Relevance rulings are reversed only for an abuse of discretion. *See Abel*, 469 U.S. at 54; *Joy v. Bell Helicopter Textron, Inc.*, 999 F.2d 549, 554 (D.C. Cir. 1993).

Indeed, continued use of a deferential standard of appellate review is implicit in the criteria for determining the admissibility of scientific expert evidence set forth in *Daubert*. To make a meaningful determination as to whether proffered expert testimony is scientifically reliable and properly applicable to the facts of a case, the district court must make preliminary factual determinations, often after an evidentiary hearing. See Fed. R. Evid. 104(a) (authorizing the trial court to make preliminary evidentiary determinations unbounded by the rules of evidence (except those concerning privileges)). The *Daubert* opinion stresses the flexible nature of this inquiry. 509 U.S. at 594-95. See also *id.* at 593 ("Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test").

The district court possesses a superior vantage point from which to evaluate the evidence. See *Eichel v. New York Cent. R.R.*, 375 U.S. 253, 256 (1963) (Harlan, J., concurring in part and dissenting in part); *Sepulveda*, 15 F.3d at 1183. The standard of review should reflect the fact that the district court is better situated to make admissibility determinations. Here, by contrast, the Eleventh Circuit afforded no deference whatsoever to the evidentiary determinations by the district court. The judgment of the court of appeals should therefore be vacated and the case remanded with instructions to review the judgment of the district court under an abuse of discretion standard.

II. DISTRICT COURTS MUST REVIEW THE SUBSTANCE OF PROFFERED EXPERT TESTIMONY IN ORDER TO DETERMINE WHETHER IT IS SCIENTIFICALLY VALID AND PROPERLY APPLICABLE TO THE CASE.

In addition to applying the incorrect standard of review, the court of appeals improperly limited the factors that may be considered by a district court in determining the

admissibility of expert testimony. This error was based on the Eleventh Circuit's erroneous conclusion that "the Federal Rules of Evidence governing expert testimony display a preference for admissibility." Pet. App. 4a. Quite to the contrary, "*Daubert* clearly requires trial judges to subject expert evidence to more penetrating pretrial scrutiny." American College of Trial Lawyers, *Standards and Procedures for Determining the Admissibility of Expert Evidence After Daubert*, 157 F.R.D. 571 (1994). Specifically, a district court must make "a preliminary assessment of [A] whether the reasoning or methodology underlying the testimony is scientifically valid and [B] whether that reasoning or methodology can be applied to the facts in issue." *Daubert*, 509 U.S. at 592-93. A mere assertion by a proffered expert that proposed testimony is based on good science is not a sufficient basis for allowing that expert to present conclusions to the jury.

A. To determine whether expert testimony has a sound scientific foundation, the trial court must determine whether the proffered expert testimony rests on knowledge acquired through the scientific method. *Daubert*, 509 U.S. at 590. This method involves empirical or other systematic testing of a hypothesis. See generally National Academy of Sciences *et al.*, 1 *Responsible Science: Ensuring the Integrity of the Research Process* 36-40 (1992); K. Popper, *The Logic of Scientific Discovery* (1959).

The scientist must collect and analyze data using rigorous and replicable techniques. J. Neale & R. Liebert, *Science and Behavior: An Introduction to Methods of Research* 7, 14 (1980). Peer reviewers must be able to analyze the study and identify potential flaws in the techniques, data, and statistical or other methods employed. Research that satisfies the rigors of peer review should provide some assurance that the specific conclusion drawn from that study is "scientific." *Responsible Science*, at 55-56. Scientists, through peer-reviewed publication, explain to the scientific community precisely how data

were collected and analyzed, and the extent to which specific hypotheses are supported by the available evidence. A. Relman, *Publishing Biomedical Research: Rules and Responsibilities*, Hastings Center Rep. at 23 (May/June 1990).

Open disclosure, critical review, and skepticism are hallmarks of the scientific process. Scientific knowledge grows only through continual questioning and criticism. Results of individual studies add to a base of scientific knowledge that accumulates incrementally over time. The process is tedious, rigorous, and slow. However, the integrity of science demands this process to ensure that perceptions, speculations, and untested theories do not become accepted as scientific truths. See K. Foster, D. Bernstein & P. Huber, *Phantom Risk: Scientific Inference and the Law* 19 (1994).

Experts who purport to offer conclusions that cannot be substantiated by research are not relying on science. For example, this practice has occurred in some silicone-gel breast implant cases. Plaintiffs in these cases have asserted that they suffer a variety of connective tissue diseases as a consequence of their exposure to the silicone-gel in their implants. However, several well-designed (albeit not conclusive) epidemiological studies have not demonstrated a clear link between silicone-gel breast implants and heightened risk of connective tissue disease. See M. Angell, *Science on Trial* 27, 100-03 (1996).[4]

In response, some putative experts have shifted the emphasis in their testimony and asserted that silicone-gel

[4] The key studies cited by Dr. Angell are: S.E. Gabriel *et al.*, *Risk of Connective-Tissue Diseases and Other Disorders After Breast Implantation*, 330 New Eng. J. Med. 1697 (1994); C.H. Hennekens *et al.*, *Self-Reported Breast Implants and Connective Tissue Diseases in Female Health Professionals*, 275 JAMA 616 (1996); J. Sanchez-Guerrero *et al.*, *Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms*, 332 New Eng. J. Med. 1666 (1995).

breast implants cause various undefined diseases. The association posited by these experts cannot be formulated as a hypothesis and cannot be tested empirically. *Id.* at 108-09. Therefore, to assert that such an association exists is not science; it is rank speculation. Witnesses should not be permitted to present such speculative testimony to juries simply because they are qualified as experts in a particular field.

Similarly, evidence by experts who have effectively become advocates for a viewpoint or for one side in a controversy (such as respondents' experts in this case) should be viewed with particular skepticism. Good science is independent and unbiased. It is undertaken in order to add to the store of medical or scientific knowledge—not to muster support for a predetermined position in litigation. For this reason, the American Medical Association's Code of Medical Ethics provides that a "medical witness must not become an advocate or a partisan" in a legal proceeding or accept compensation "contingent upon the outcome of litigation." AMA, *Code of Medical Ethics* § 9.07.[5]

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[5] Opinion 9.07, entitled "Medical Testimony," provides:

> As a citizen and as a professional with special training and experience, the physician has an ethical obligation to assist in the administration of justice. If a patient who has a legal claim requests a physician's assistance, the physician should furnish medical evidence, with the patient's consent, in order to secure the patient's legal rights.
>
> Medical experts should have recent and substantive experience in the area in which they testify and should limit testimony to their sphere of medical expertise. Medical witnesses should be adequately prepared and should testify honestly and truthfully to the best of their medical knowledge.
>
> The medical witness must not become an advocate or a partisan in the legal proceeding. The attorney for the party who calls the physician as a witness should be informed of all favorable and unfavorable information developed by the physician's evaluation of the case. It is unethical for a physician to accept compensation that is contingent upon the outcome of litigation.
>
> AMA, *Code of Medical Ethics* § 9.07 (issued June 1986, updated June 1996).

"[W]hen an expert prepares reports and findings before being hired as a witness, that record will limit the degree to which he can tailor his testimony to serve a party's interests." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir.) (on remand), *cert. denied*, 116 S. Ct. 189 (1995). Research conducted and opinions formed "solely for the purpose of testifying are more likely to be biased toward a particular result." *E.I. du Pont de Nemours & Co. v. Robinson*, 923 S.W.2d 549, 559 (Tex. 1995). A court should be reluctant to admit purported expert testimony that relies on such evidence absent other sources of scientific corroboration.

B. In addition to being grounded in good scientific methodology, expert evidence must properly be applicable to the particular case. *Daubert*, 509 U.S. at 591-92 ("Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility"). To meet this requirement in cases involving scientific evidence, the underlying data must be sufficient to support the conclusion that the testifying expert intends to present to the jury. In other words, the data must be "of a type reasonably relied upon by experts in the particular field in forming opinions and inferences upon the subject. . . ." Fed. R. Evid. 703. In determining whether the data upon which an expert relies provide a scientifically sound foundation for the expert's proffered testimony, a trial court should consider both the nature of the study and the type of conclusions that it will support.

1. Scientific data can be gathered in a number of ways. Differences in the type of study and the size and composition of the database affect the nature and strength of conclusions that can be drawn. For instance, epidemiological

evidence is of greater scientific value than anecdotal observation.[6] Epidemiological studies gather a greater range of data and therefore can better account for chance occurrences and other variables that might unexpectedly affect results. Moreover, epidemiological data can be reviewed and replicated by other scientists so that conclusions can be confirmed.[7] In contrast, anecdotal evidence makes no effort to control for variables that might affect a database.

2. Scientific studies designed to address only limited issues do not support far-reaching conclusions on causation. Scientific knowledge grows only through continual questioning and criticism. Results of individual studies add to a base of scientific knowledge that accumulates incrementally over time. Indeed, some scientifically valid studies do no more than suggest subjects for future research.

While a study may produce a narrow finding that would be of interest in a particular field of research, it may not support broad conclusions with respect to causation. An expert witness should not be allowed to testify to such conclusions based on an inadequate scientific foundation. Such testimony would not be based on scientific knowledge and would not comport with scientific method. Rather, the expert would be engaging in precisely the sort of speculation forbidden by *Daubert*.

In the present case, respondents' experts relied on two studies in which infant mice injected with high concentrations of PCBs developed cancer. Animal studies may, in some circumstances, provide strong support for a scientific

[6] *See generally* U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services* 1 (2d ed. 1996) (ranking different types of clinical studies to give greater evidentiary weight to "study designs that are, in general, less subject to bias and misinterpretation").

[7] Even one well-designed epidemiological study may have more scientific weight than another because, statistically, a higher confidence level can be assigned to its results. *Daubert*, 509 U.S. at 594.

conclusion.[8] However, if the two studies of mice described above constituted the only evidence presented in support of the conclusion that PCB exposure promotes a specific type of lung cancer in humans, that conclusion should not be admitted in evidence. The differences between humans and mice, as well as the route and dose of PCB exposure, are so great that it is not scientifically sound to extrapolate to the more general conclusion that occupational exposure to PCBs promoted respondent's specific type of lung cancer.

III. A TRIAL COURT DOES NOT USURP THE DUTIES OF THE TRIER OF FACT BY ADMITTING ONLY EXPERT OPINIONS WITH A SOUND SCIENTIFIC BASIS.

The Eleventh Circuit gave two reasons for barring district courts from examining the substantive support for expert evidence. First, the court expressed concern that such an approach would require judges to act as scientists. Second, the court warned that such substantive consideration would usurp the duties of the trier of fact. Pet. App. 7a-8a, 11a-12a. Both concerns are misplaced.

A. Judges are routinely called upon to determine whether there is an adequate foundation for testimony and to exclude testimony that lacks such support. They perform precisely the same function in determining whether there is an adequate scientific foundation for expert testimony.

[8] The extrapolation of experimental results from animals to humans is controversial. Although positive findings in animals may be suggestive, the results are not necessarily equivalent to findings in humans. This is particularly true when significant discrepancies occur between animal and human exposures in terms of dose, route of administration, and physiological responses. To fill data gaps, scientists look to evidence from epidemiological studies of exposed and nonexposed populations. Ultimately, making a determination of cause and effect requires studies from multiple scientific disciplines such as biochemistry, molecular biology, genetics, toxicology, and epidemiology. *See* B. Ames & L. Gold, *Chemical Carcinogenesis: Too Many Rodent Carcinogens*, 87 Proceedings of the National Academy of Science 7772 (Oct. 1990).

Many of these determinations can be made simply as a matter of common sense.[9] The mice study example presented above is such a case. It should be apparent that studies in which infant mice developed cancer after being injected with high doses of PCBs do not, taken alone, support a reasoned scientific conclusion that occupational exposure to minute quantities of PCBs promotes a specific type of lung cancer in humans.

Moreover, the Federal Rules of Evidence provide a specific mechanism for making expert assistance available to trial judges. Rule 706 provides that the court may on its own motion appoint an independent expert witness to advise the court on whether the scientific analysis underlying an expert's proffered testimony is consistent with good scientific practices. Rule 706 has rarely been invoked by trial court judges. *Amicus* submits, however, that increased use of the process envisaged by Rule 706 will assist judges in fulfilling their role as gatekeepers by distinguishing between good science and speculation dressed up to pass as science. See generally *Science on Trial* at 205.

B. The judge, acting as a gatekeeper of proffered scientific evidence, does not encroach on the authority of the jury. *Amicus* is not proposing the exclusion of minority views of scientific evidence or suggesting that judges choose between competing scientific theories. Rather, *amicus* urges only that judges require proponents of expert testimony to demonstrate that the testimony has a sound scientific basis. See *Claar v. Burlington N. R.R.*, 29 F.3d 499, 501 (9th Cir. 1994) (court may inquire "into the reliability of the methods and reasoning underlying the conclusions" in the proposed testimony).

Expert witnesses have a special status under the Federal Rules of Evidence. They need not testify from per-

[9] Other issues can be resolved by reference to the *Reference Manual on Scientific Evidence* prepared by the Federal Judicial Center.

sonal knowledge and the basis for their opinions need not be admissible. Fed. R. Evid. 705. Moreover, experts, unlike other witnesses, generally may opine on the "ultimate issues" to be decided by the jury. Fed. R. Evid. 704.

Partially in recognition of the special status of experts and the special risks their testimony engenders, Rule 702 establishes a higher standard than mere relevance for the admissibility of expert testimony, especially testimony by scientific experts. See *Daubert*, 509 U.S. at 592. The evidence must "assist the trier of fact." Fed. R. Evid. 702. Expert testimony that purports to offer scientific conclusions when the underlying research is flawed or does not support the conclusions proffered, does nothing to assist the trier of fact. Speculation—even speculation by someone with scientific credentials—is still only speculation. What is worse, the expert's testimony is speculation cloaked in the garb of seemingly impressive academic credentials. The risk that this speculation will be considered by the trier of fact as entitled to more weight than common sense would dictate is why the trial court's role as a gatekeeper is so vital.

IV. THE ADMISSION OF "EXPERT" OPINIONS THAT DO NOT HAVE SOUND SCIENTIFIC SUPPORT HAS AN ADVERSE EFFECT ON PHYSICIANS, THEIR PATIENTS, AND SOCIETY.

In addition to the plain language of Rule 702, sound public policy counsels that district courts have the latitude to exclude expert testimony that offers conclusions lacking in scientific support. The introduction of evidence not grounded in scientific knowledge may, of course, lead to inequitable judgments in individual cases. *Cf.* Fed. R. Evid. 102 (the Federal Rules of Evidence should be construed to further the goal of ascertaining the truth and providing a just determination of a case). But, even more fundamentally, permitting civil damage actions to be decided on the basis of opinions not grounded in science

will, over time, have a detrimental effect on patients and on society generally.

Examples from recent history demonstrate that, as a result of legal judgments based upon invalid medical or scientific opinions, medical professionals and their patients have been deprived of a number of beneficial treatment options. Bendectin is a prime example of a beneficial drug, approved as "safe and effective" by the Food and Drug Administration, that is no longer available to physicians and patients because of liability imposed on the basis of unscientific expert testimony.[10]

Similarly, the FDA still considers the Copper-7 intrauterine device ("IUD") to be "safe and effective."[11] However, a number of federal courts have allowed experts to offer opinions without basis in scientific methodology suggesting that this IUD is far more dangerous than any legitimate study has demonstrated. See, *e.g.*, *Amore v. G.D. Searle & Co.*, 748 F. Supp. 845 (S.D. Fla. 1990). Although the manufacturer prevailed in a number of cases alleging injury based upon the use of this IUD, see *id.* at 848 n.3, by 1986, it became impossible to purchase insurance for the product.[12]

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[10] More than 30 scientific studies have been conducted to determine whether any statistically significant correlation exists between the use of this drug and limb defects. No study has demonstrated such a correlation. *See* J. Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301 (1992) (summarizing the findings).

[11] Use of this IUD involves a very slight risk of pelvic inflammatory disease.

[12] The adverse impact of unfounded liability has "contributed significantly to the climate of disincentives for the development of contraceptive products." National Research Council & Institute of Medicine, *Developing New Contraceptives—Obstacles and Opportunities* 141 (L. Mastroianni *et al.* eds., 1990). "In the early 1970s, there were 13 pharmaceutical companies actively pursuing research in contraception and fertility. Now, only one US company conducts contraceptive and fertility research." AMA Board of Trustees,

The admission of unscientific testimony also has affected the availability of many vaccines. All but one manufacturer stopped making the vaccine for diphtheria, tetanus, and pertussis (whooping cough) following a series of lawsuits based upon expert "opinion" that the pertussis portion of the vaccine might in fact be causing encephalopathy (an inflammatory brain disease). See J. Cherry, *"Pertussis Vaccine Encephalopathy": It Is Time to Recognize It as the Myth That It Is*, 263 JAMA 1679 (1990). Thorough epidemiological studies have demonstrated that there is no statistically significant relationship between the vaccine and encephalopathy. See M. Griffin *et al.*, *Risk of Seizures and Encephalopathy After Immunization With the Diphtheria-Tetanus-Pertussis Vaccine*, 263 JAMA 1641 (1990).

Unscientific judgments also have directly affected the provision of medical services. In particular, many obstetricians have been subject to successful tort claims attributing various ailments, including cerebral palsy, to their improper handling of deliveries and their failure to perform cesarean sections.[13] See, *e.g.*, *Low v. United States*, 795 F.2d 466 (5th Cir. 1986); *Nemmers v. United States*, 612 F. Supp. 928 (C.D. Ill. 1985), *vacated on other grounds*, 795 F.3d 628 (7th Cir. 1986). The available scientific evidence, however, provides no support for the hypothesis that cerebral palsy results from improper delivery techniques.[14]

Impact of Product Liability on the Development of New Medical Technologies, at 9 (June 1988).

[13] Soaring malpractice premiums for obstetricians and family physicians who practice obstetrics have driven many such physicians out of that practice, especially in rural areas. *See* American College of Obstetricians and Gynecologists, *Professional Liability Insurance and Its Effects; Report of a Survey of ACOG's Membership* (1992).

[14] Indeed, it is increasingly clear that obstetricians have virtually no ability to prevent cerebral palsy through either the use of

In short, the admission of unscientific medical "opinion" furthers no legitimate scientific, legal, or social purpose. To the contrary, if opinions that lack a scientific foundation are admitted into evidence, then some judgments inevitably will be based on those opinions. And, as a result, the practice of medicine will be influenced by these judgments, to the detriment of the health of the public. Such a perverse result is at odds with the goals of the Federal Rules of Evidence and of the judicial process itself, and makes the law the enemy of good science.

Rule 702 does not require such harmful consequences. To the contrary, the Rule's language and structure evince an intent to promote the truth-finding process both inside and outside the courtroom by requiring expert opinion to be based on scientifically accepted methods. District courts should be allowed to exercise their discretion under Rule 702 to exclude testimony that is based on bad science or that proffers conclusions that cannot be supported based on available scientific data.

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electronic fetal monitoring devices or more frequent cesarean sections. *See* K. Shy *et al., Effects of Electronic Fetal-Heart-Rate Monitoring, as Compared with Periodic Auscultation, on the Neurologic Development of Premature Infants*, 322 New Eng. J. Med. 588 (1990).

CONCLUSION

The judgment of the court of appeals should therefore be reversed.

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
and MONSANTO COMPANY,
Petitioners,

v.

ROBERT K. JOINER and KAREN P. JOINER,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

---

BRIEF OF *AMICI CURIAE*, THE PRODUCT LIABILITY ADVISORY COUNCIL, INC., THE NATIONAL ASSOCIATION OF MANUFACTURERS, AND MEDMARC, IN SUPPORT OF PETITIONERS

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IN THE

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OCTOBER TERM, 1996

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Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF OF *AMICI CURIAE*, THE PRODUCT LIABILITY ADVISORY COUNCIL, INC., THE NATIONAL ASSOCIATION OF MANUFACTURERS, AND MEDMARC, IN SUPPORT OF PETITIONERS

INTEREST OF *AMICI CURIAE* *

The Product Liability Advisory Council, Inc. ("PLAC") is a nonprofit corporation with 114 corporate members from a broad cross-section of American industry, and the

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* Pursuant to S. Ct. R. 37.6, counsel for *amici curiae* state that this brief was not authored in whole or in part by a party and that no person or entity, other than the *amici curiae*, its members and its counsel, made a monetary contribution to the proportion or submission of this brief.

product liability lawyers who represent them. Its corporate members include manufacturers and sellers in industries ranging from electronics to automobiles to pharmaceutical products and medical devices.[1] PLAC's purpose is to file *amicus* briefs on behalf of its members on issues that affect the law of product liability. PLAC has submitted many *amicus* briefs in state and federal courts, including this Court.

The National Association of Manufacturers (the "NAM") is the nation's oldest and largest broad-based industrial trade association. Its more than 14,000 member companies and subsidiaries, including 10,000 small manufacturers, employ approximately eighty-five percent of all manufacturing workers and produce over eighty percent of the nation's manufactured goods. More than 158,000 additional businesses are affiliated with the NAM through its Associations Council and National Industrial Council. The NAM's interest on issues that affect the law of product liability is identical to the interest of PLAC.

MEDMARC is a specialty insurer which provides product liability coverage for medical device manufacturers. Owned and controlled by its members, MEDMARC was founded in 1979 in response to volatile conditions in the commercial insurance market for product liability insurance. MEDMARC's membership includes approximately 550 manufacturers and distributors of medical devices and diagnostic products.

The issue before this Court is the proper standard of review of trial court decisions admitting or excluding expert evidence *Amici curiae* are well-situated to address this issue. Their members are subject to defending an increasing number of product liability lawsuits. Expert testimony is the rule, not the exception in those cases.

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[1] A list of PLAC's corporate members appears in the appendix hereto.

Amici curiae regularly face appeals on issues relating to the propriety of expert evidence.[2]

SUMMARY OF ARGUMENT

The standard of review for trial court decisions concerning the admissibility of evidence including admission or exclusion of expert testimony has been the deferential abuse of discretion standard. The Eleventh Circuit in *Joiner v. General Electric*, 78 F.3d 524, 535 (11th Cir. 1996) applied a "particularly stringent" standard of review to the trial court's exclusion of expert testimony, even though the trial court did not misapprehend the law applicable to the issue. It created a double standard of review, dependent on whether the trial court admitted or excluded the evidence. Other courts have suggested multiple standards of review, dissecting the admissibility ruling into components in which different standards are applied. Still other courts apply multiple standards depending upon the final outcome of the admissibility decision, namely whether it results in summary judgment or directed verdict.

What is the proper standard of review for a trial court's decision on the admission or exclusion of evidence from experts? This is the limited issue before the Court. *Amici* agree with this Court that the trial court is best situated and fully capable of fulfilling the gatekeeper role more fully defined in *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993). Those duties vary little from the obligations successfully carried out by the trial courts prior to *Daubert*. It is an unnecessary waste of time and resources for appellate courts to revisit the admissibility determination as if taking a first look at the matter.

While the Federal Rules of Evidence freed the trial courts from the strictures of some common law exclu-

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[2] The Parties' written consent to the submission of this brief is on file with the Court.

sionary rules and formalistic requirements, thus "liberalizing" the admission of evidence, the changes in the law of evidence contained within the Rules provide no justification for abandoning the traditional abuse of discretion standard of review. The "liberal thrust" of the Rules does not suggest that the reliability gate has been cracked open to permit unreliable evidence to slip through. The parameters within which evidence must fall to be deemed reliable have been merely broadened and clarified. The "liberal thrust" of the Rules is in fact related to their flexibility. With that flexibility is the recognition that the trial court has broad discretion with respect to application of the Rules to each particular case. Adoption of a "particularly stringent" standard of review will not encourage trial judges to be flexible.

If the resolution of the admissibility question is fatal to a party's case, and results in summary judgment or a directed verdict, that is no grounds to impose a stricter standard of review than abuse of discretion. The trial courts have had little difficulty resolving the admissibility issues first, and then evaluating the merits of dispositive motions. The trust this Court has in the trial courts to fulfill the gatekeeper role is well-placed. In *Daubert*, the trial court's discretion was broadened to consider additional factors in evaluating the reliability of testimony proffered by experts. That discretion must be respected by the appellate courts faced with challenges to the trial court's rulings. To do otherwise, and permit the appellate court to substitute its judgment for that of the trial court, strains against judicial precedent and wastes judicial resources.

This court should reaffirm that the abuse of discretion standard applies to all trial court determinations of the admissibility of expert evidence.

ARGUMENT

I. THE ABUSE OF DISCRETION STANDARD OF REVIEW SHOULD BE CONSISTENTLY APPLIED WHETHER THE TRIAL COURT ADMITS OR EXCLUDES EXPERT EVIDENCE, OR WHETHER A DECISION TO EXCLUDE RESULTS IN SUMMARY JUDGMENT OR DIRECTED VERDICT

A. Introduction

The decision to admit or exclude expert evidence may be based on evidence rules 401, 402, 403, 404(b), 702, 703, and/or a variety of statutes. Further, the effect of an evidentiary ruling may vary, from a simple limitation on the scope of certain evidence to complete exclusion of a witness. In some cases, summary judgment or directed verdict may follow, if the evidence excluded is crucial to a party's case.

Until very recently, circuit courts have unanimously evaluated all lower court evidentiary decisions for abuse of discretion or manifest error.[3] The reasons for according such deference to the trial court are manifest: 1) the trial judge is in the best position to evaluate the proffered testimony in the context of the entire case; 2) the trial judge is called upon to make so many evidentiary rulings in the course of a single case that the appellate courts can ill afford to carry the burden of reviewing every such ruling; 3) a heightened level of review of each evidentiary ruling will increase the frequency of appeals. Rulings on the admissibility of expert testimony are based largely on helpfulness to the jury, which of necessity, require the exercise of discretion. In the past, the standard of review has not been dependent upon whether the evidence was admitted or excluded. It did not matter which evidence rules formed the basis for the decision, the stage in the

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[3] 4 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence*, ¶ 702.02[2] (2d ed. 1997) at 702-7: "There is no substantive difference between 'manifest error' and 'abuse of discretion.'"

proceeding when the issue was raised, or whether the decision led to the grant of a dispositive motion; the rulings were reviewed for abuse of discretion.

To apply different standards of review according to the result of the decision or the precise basis enunciated for the decision, as some circuits now do, is to end decades of uniform jurisprudence, and to add complexity and confusion to an issue that needs clarity and consistency. The abuse of discretion standard has worked for over a century because it fosters finality of the trial court's decision, recognizes the trial court is better situated to make the decision, is simple to apply and makes sense. The *Daubert* decision does not suggest that a double standard is appropriate. To the contrary, this Court reaffirmed its confidence in the trial court to determine the reliability of expert evidence. The decision to admit or exclude that testimony has always involved the analysis of the reliability of the evidence, and now carries the same ramifications as before. Because expert evidence may be admitted or excluded under a variety of rules, the imposition of a stricter scrutiny for trial court rulings which exclude evidence under Rule 702 creates a pigeon hole for review which ignores the interdependency of the Rules.

B. Admission Versus Exclusion

In *Joiner*, the Eleventh Circuit created a double standard when it applied "a particularly stringent standard of review to the trial judge's exclusion of expert testimony," 78 F.3d at 529,[4] thus advocating a lesser standard where the trial court *admits* expert testimony. The Rules themselves provide no support for a double standard; they are neutral with respect to admission or exclusion. Commentators have said correctly that the Rules provide the trial judge with "broad discretion to admit or exclude testimony under the test of 'helpfulness.'" J. Weinstein, *Weinstein's Federal Evidence*, ¶ 702.02[02], (2d ed. 1997).

[4] It applied a new standard because the rules "display a preference for admissibility." *Id.* at 529.

In suggesting that "a hard look" should be taken, appellate courts have expressed their concern about trial court decisions to admit or exclude: the Fifth Circuit has been concerned about the trial courts letting too much in [5]; the Third and Eleventh Circuits are concerned about the trial courts keeping too much out.[6] If the *Joiner* double standard is applied, the trial courts will be encouraged to circumvent their gatekeeper duties, find a way around the reliability gate, and admit the junk science *Daubert* and the Rules meant to exclude. If a stricter standard were applied to admission decisions, courts may escape scrutiny by excluding that evidence which is sufficiently reliable to meet the helpfulness standard of Rule 702.

The problems with a double standard are compounded by some circuits which apply a stricter standard looking to the end result of the trial court's admissibility determination, not the foundation for it. Thus, in *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 750 (3d Cir. 1994), the Third Circuit stated:

> [W]hen the district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment, we will give them a "hard look" . . . to determine if a district court has abused its discretion in excluding evidence as unreliable.

[5] *In Re Air Crash Disaster at New Orleans*, 795 F.2d 1230, 1234 (5th Cir. 1986): "In sum, we adhere to the deferential standard for review of decisions regarding the admission of testimony by experts. Nevertheless, we take this occasion to caution that the standard leaves appellate judges with a considerable task. We will turn to that task with a sharp eye, particularly in those intances, hopefully few, where the record makes it evident that the decision to receive expert testimony was simply tossed off to the jury under a 'let it all in' philosophy. Our message to our able trial colleagues: it is time to take hold of expert testimony in federal trials."

[6] *See In re: Paoli R.R. Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994) and *Joiner, supra*.

See also Ambrosini v. Labarraque, 101 F.3d 129, 132 (D.C. Cir. 1996) (applying de novo standard of review because decision to exclude testimony resulted in summary judgment). This view fails to recognize that the trial courts have had little trouble evaluating the admissibility of evidence first, and considering subsequently whether summary judgment or directed verdict are proper.[7] *See, e.g., Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 320 (7th Cir. 1996); *Buckner v. Sam's Club, Inc.*, 75 F.3d 290, 292-93 (7th Cir. 1996); *Barrett v. Atlantic Richfield Co.*, 95 F.3d 375, 383 (5th Cir. 1996).

There is no reason to apply different standards of review to decisions that result in exclusion instead of admission. We know that only reliable testimony is admissible; the suggestion that a stricter standard is needed when testimony is excluded misconstrues the "liberal thrust" of the Rules. The courts that impose heightened scrutiny to decisions excluding testimony recite that the Rules changed the criteria for admission of some kinds of evidence, and liberalized admission. *See, e.g., In re Paoli, supra; Joiner, supra.* The notion that the federal rules liberalized the standards of admission comes from the abrogation of certain restrictive common law doctrines and technicalities concerning evidence, including the foundation required for expert testimony.[8] *See* Federal Rules of Evidene 702, 703, 704, 705; *Arcoren v. United States*, 929 F.2d 1235, 1239 (8th Cir. 1991); *Krist v. Eli Lilly & Co.*, 897 F.2d 293, 298 (7th Cir. 1990); *Soden v. Freightliner Corp.*, 714 F.2d 498 (5th Cir.

[7] *See*, Fed. R. Civ. P. 56(e). Motions for summary judgment depend upon the existence of admissible evidence.

[8] Meeting the goals of the Rules has greater significance than technical perfection. F.R.E. 102. The Rules merged the concepts of materiality and relevance, eliminated the needless formality of the "best evidence" rule, eliminated the "uncalled witness rule," and permit experts to base their opinions on evidence which may be inadmissible if it is information reasonably relied upon by experts in the field. *See* generally Weinstein, *supra*, at ¶ 102.02[1]-[5]

1983); *Seese v. Volkswagenwerk A.G.*, 648 F.2d 833, 844 (3d Cir. 1981); *Bauman v. Centex*, 611 F.2d 1115, 1120 (5th Cir. 1980); *Merit Motors, Inc. v. Chrysler Corp.*, 569 F.2d 666, 672-73 (D.C. Cir. 1977); *United States v. Addison*, 498 F.2d 741, 744 (D.C. Cir. 1974). Recall that prior to the adoption of the Rules, opinion testimony was generally disfavored because opinions invaded the province of the jury. Further, if opinion testimony was permitted it was severely restricted by devices like the hypothetical question, or unrealistic foundation requirements. See 4 J. Weinstein, *Weinstein's Federal Evidence*, ¶ 702.02[1], 703.02, 03[1] (2d ed. 1997). The Rules were crafted to address these problems. However, the Rules favor admissibility of *reliable* evidence only; the "liberal thrust" of the federal rules does not suggest that the gates have been lowered to admit unreliable evidence.

The first Supreme Court decision to address the standard of review of expert testimony admissibility was *Spring Co. v. Edgar*, 99 U.S. 645, 658 (1878), in which the Court stated: "Cases arise where it is very much a matter of discretion with the court whether to receive or exclude the [expert] evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous." Next, *Salem v. United States Lines Co.*, 370 U.S. 31, 35 (1962), reaffirmed that "the trial judge has broad discretion in the matter of the admission or exclusion of expert evidence, and his action is to be sustained unless manifestly erroneous." Thus, the same discretionary standard applies regardless of the result of the trial court's decision, i.e., admission or exclusion.

This Court in *Daubert* validated the exercise of that discretion when it explicitly entrusted to the trial courts the gatekeeper role, and expressed its confidence in federal judges' ability to undertake the *Daubert* analysis.[9] No

[9] *Daubert v. Merrell Dow Pharms., supra*, set forth the factual matters a trial court should weigh in deciding on expert admissi-

mention was made of restricted discretion if the decision was to exclude evidence. Indeed, in *In re Joint Eastern & Southern Dist. Asbestos Litigation*, 52 F.3d 1124, 1132 (2d Cir. 1995), the Second Circuit opined that "[t]he Daubert Court significantly changed the standards governing the admissibility of scientific evidence by *expanding* district courts' discretions to evaluate the reliability and relevance of contested evidence." (emphasis added) *See also* 1 Steven Alan Childress & Martha S. Davis, *Federal Standards of Review*, at 4.02, at n. 12 (2d ed. Supp. 1996) (With respect to application of *Daubert*, "it is apparent that most of the decision making is located in the trial judge, which is consistent with . . . abuse of discretion review"); G. Michael Fenner, *The Daubert Handbook: The Case, Its Essential Dilemma, and Its Progeny*, 29 Creighton L. Rev. 939, 1028 (1996) ("The standard of review of Daubert testing on appeal is pretty clear. Though the words vary, the meaning is the same: almost all of the cases say the standard is broad or deferential, it is a clearly erroneous standard, it looks for manifest or clear abuse of discretion").

Implicitly acknowledging this expanded discretion, almost all the circuits have consistently applied the deferential review in post-*Daubert* cases involving Rule 702. *See Lust by & Through Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 597-98 (9th Cir. 1996) (stating that the district court did not abuse its discretion in concluding that, under *Daubert*, the methodology underlying the proffered expert witness's testimony was not scientific); *Compton v. Subaru of Am., Inc.*, 82 F.3d 1513, 1517 (10th

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bility. *Daubert* requires district judges to act as gatekeepers to ensure that scientific evidence is both relevant and reliable. 509 U.S. 589. This entails two inquires: whether the reasoning and methodology underlying the testimony is scientifically valid, and whether the reasoning and methodology can properly be applied to the facts. *Id.* at 592-93. The Supreme Court is "confident that federal judges possess the capacity to undertake this review." *Id.* at 593.

Cir. 1996) *cert. denied* —— U.S. —— (1997) (upholding trial court's admission of expert testimony under an abuse of discretion standard); *United States v. Shay*, 57 F.3d 126, 132 (1st Cir. 1995) ("A district court's decision to admit or exclude expert testimony is entitled to great deference"); *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1042 (2d Cir. 1995) ("The decision to admit expert testimony is left to the broad discretion of the trial judge and will be overturned only when manifestly erroneous."); *Government of the Virgin Islands v. Sanes*, 57 F.3d 338, 341 (3d Cir. 1995) ("Whether to allow scientific or technical expert testimony . . . is within the discretion of the district court and is reviewed only for abuse."); *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1384 (4th Cir. 1995) ("Daubert clearly vests the district courts with discretion to determine the admissibility of expert testimony."); *Pedraza v. Jones*, 71 F.3d 194, 197 (5th Cir. 1995) (stating that "the district court did not abuse its discretion" in concluding that the proffered expert testimony did not satisfy Daubert's reliability requirements); *American & Foreign Ins. Co. v. General Electric Co.*, 45 F.3d 135, 137 (6th Cir. 1995) (trial court's admission or exclusion of expert evidence is to be sustained unless "manifestly erroneous"); *Deimer v. Cincinnati Sub-Zero Prods., Inc.*, 58 F.3d 341, 344 (7th Cir. 1995) (decision to allow expert testimony is within the broad discretion of the trial judge and is to be sustained on appeal unless "manifestly erroneous."); *Pestel v. Vermeer Mfg. Co.*, 64 F.3d 382, 384-85 (8th Cir. 1995) ("The [District] Court concluded that the testimony was not scientifically valid and would not aid the jury in its fact finding. We do not find that the District Court abused its discretion in any of its analysis."); *Joy v. Bell Helicopter Textron, Inc.*, 999 F.2d 549, 567-68 (D.C. Cir. 1993) (notwithstanding abuse of discretion standard, trial court erred by allowing certain expert testimony).

C. The Same Standard Should Be Applied Regardless of Dependent Motions: Summary Judgment or Directed Verdict Are Not Disfavored

Every ruling on evidence affects the outcome of the case to a greater or lesser degree. The standard of review should not change where the exclusion of expert testimony results in summary judgment or a directed verdict in favor of the moving party. In the first instance, two separate legal inquiries are involved. Thus, in *Lust, supra*, 89 F.3d at 596-97, the Ninth Circuit stated:

> We review a grant of summary judgment de novo, . . . and an F.R.E. 702 ruling for an abuse of discretion. The abuse of discretion standard applies to an F.R.E. 702 ruling even though the ruling was dispositive of a motion for summary judgment.

Similarly, in *Duffee by and Through Thornton v. Murray Ohio Mfg. Co.*, 91 F.3d 1410, 1411 (10th Cir. 1996), the Tenth Circuit affirmed summary judgment in favor of the defendant manufacturer after upholding the exclusion of the plaintiffs' expert witness under an abuse of discretion standard. The *Duffee* Court noted that a *de novo* standard applies to summary judgment decisions, but held that the evidentiary admissibility decisions of the trial court are properly reviewed under the traditional abuse of discretion standard. *Id.*

There is no need for different standards of review of the admission decision is fatal to a party's case. Summary judgments and directed verdicts rise or fall depending on what admissible evidence has been presented to make a *prima facie* case. Appellate courts have no trouble addressing first the admissibility of evidence under an abuse of discretion standard, then the summary judgment or directed verdict under a *de novo* standard. Thus, numerous appellate courts apply a deferential standard of review

to *Daubert* rulings, even though summary judgment resulted.[10]

Trial courts have shown, again and again, that this Court did not err in entrusting the *Daubert* analysis, in the first place, to the lower courts, regardless of whether the trial judge admitted or excluded the expert evidence. There is no dearth of cases in which the trial judge has performed a thorough and well-reasoned *Daubert* analysis, and decided to admit proffered expert evidence. *See, e.g., Kieffer v. Weston Land, Inc.*, 90 F.3d 1496 (10th Cir. 1996); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995); *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968 (8th Cir. 1995); *United States v. Quinn*, 18 F.3d 1461 (9th Cir. 1994); *Virgin Island v. Penn*, 838 F. Supp. 1054 (D.V.I. 1993); *Benedi, supra*; *McCullock, supra.*

Trial courts have performed the *Daubert* analysis in a reasonable and careful manner when they have decided to

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[10] *See, e.g., Goewey v. U.S.*, 1997 U.S. App. LEXIS 1528 at *6-7 (4th Cir. Jan. 30, 1997) ("we cannot say that the district court abused its discretion in excluding this expert testimony as 'not sufficiently reliable' under *Daubert*, . . . or that it erred in rejecting the expert testimony under Baughman. Accordingly, we affirm the district court's grant of summary judgment"); *Wintz by & Through Wintz v. Northrop Corp.*, 110 F.3d 508, 512 (7th Cir. 1997) ("Trial judges enjoy wide latitude and discretion when determining whether to admit expert testimony, and the district court's decision concerning admissibility of such testimony (provided it follows the Daubert methodology) will not be disturbed unless 'manifestly erroneous'"; summary judgment affirmed); *Barrett, supra*, 95 F.3d at 383 ("because we find no abuse of discretion in the court's striking of the expert testimony, and no additional relevant summary judgment evidence, we affirm the court's order granting Defendants' motion for summary judgment as to these claims"); *Rosen, supra*, 78 F.3d at 320 ("The district court was within its discretion in concluding that the scientific evidence of causation that the plaintiff offered was not admissible, and therefore in dismissing the suit"); *Buckner, supra*, 75 F.3d at 292, 294 ("We review a district court's rulings on evidentiary matters for abuse of discretion, giving the trial judge much deference"; summary judgment affirmed).

exclude expert evidence, as well. *See, e.g., Peitzmeier v. Hennessy Indus., Inc.*, 97 F.3d 293, 297 (8th Cir. 1996); *Cummins v. Lyle Indus.*, 93 F.3d 362, 367-70 (7th Cir. 1996); *American & Foreign Ins. Co., supra*; *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194 (5th Cir. 1996); *Barrett, supra*; *Goewey, supra*; *Brown v. Miska*, 1995 U.S. Dist. LEXIS 17197 at *11 (S.D. Tex. July 19, 1995), *aff'd without op.*, 96 F.3d 1445 (5th Cir. 1996); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996); *Arrendondo v. Uniroyal Goodrich Tire Co.*, 1995 U.S. Dist. LEXIS 19943 (D. Ariz. Aug. 14, 1995); *Hopkins v. NCR Corp.*, 1994 U.S. Dist. LEXIS 17273 at *20, 22 (M.D. La. Nov. 17, 1994); *Stanczyk v. Black & Decker, Inc.*, 836 F. Supp. 565 (N.D. Ill. 1993). The fact that more appellate cases deal with the exclusion of evidence should not come as a surprise, and provides no justification for a stricter standard of review. A losing party is more likely to appeal an exclusion decision than an admission ruling involving testimony found to be reliable.

D. No Reason to Distinguish Rule 702 From Other Evidence Rules

The Rules of Evidence are interdependent, and require flexibility in application. *See generally* F.R.E. 102, Weinstein, *supra* at ¶ 102.02[1],[2]. The Rules require the trial courts to weigh competing interests, working toward fulfilling the goal "that the truth may be ascertained and the proceedings justly determined." F.R.E. 102. Those objectives require the court to exercise discretion; that discretion is broad when the trial court is proceeding, as Rule 102 directs, to balance the objectives of the Rules in a particular case. Weinstein, *supra* at ¶ 102.03. The trial court must balance competing interests in every evidence ruling it makes.

Rule 702 determinations turn on whether the evidence will be helpful to the jury. Rule 403 determinations are similarly governed. There is no mechanical formula to

determine helpfulness or relevance. The exercise of discretion is inherent in both rules. If an abuse of discretion standard is appropriate anywhere, it is appropriate for decisions concerning the admissibility of expert evidence.

There is no reason to distinguish between the standard of review of lower court expert admissibility determinations from other evidentiary decisions. In each instance, the trial court applies the Rules to the facts on a case by case basis. Admissibility decisions based on Rules 702 or 703 are much like decisions based on Rule 403. Rule 403 is reviewed for abuse of discretion, even though application of that Rule may result in preclusion of evidence, which itself may result in summary judgment or a directed verdict. Thus, in *Lucas v. Bechtel Corp.*, 800 F.2d 839, 849 (9th Cir. 1986), the Ninth Circuit upheld the trial court's exclusion of evidence pursuant to Rule 403, stating: " 'Our review of rulings on evidence is limited to abuse of discretion, even in the context of appeals from a directed verdict.' [citations omitted] We find no abuse of discretion."

Several months ago, this Court affirmed that the standard of review applicable to evidentiary rulings of the district court is abuse of discretion. *Old Chief v. United States*, —— U.S. ——, 117 S. Ct. 644, 647 n.1 (1997) (*citing United States v. Abel*, 469 U.S. 45 (1984)). In *Old Chief*, the Court applied the abuse of discretion standard to a trial court's Rule 403 ruling that evidence of a criminal defendant's prior crime was admissible. Similarly, *Abel* involved a trial court's admission of evidence concerning the defendant's involvement in a prison gang. These cases show that even when a defendant's liberty is at stake, the trial court's evidentiary rulings are given deferential review.

Case law is replete with examples of courts applying an abuse of discretion standard to evidentiary decisions, which of necessity involve mixed questions of law and

fact.[11] That standard has been applied even in cases where summary judgment or a directed verdict has resulted. *See Hawkins v. Hennepin Technical Center*, 900 F.2d 153, 155 (8th Cir. 1990) (Eighth Circuit reversed summary judgment for the defendant in a disparate treatment sex discrimination case, holding that the district court abused its discretion under Rule 402 in barring the plaintiff from introducing evidence of prior sexual harassment of herself and other employees); *Gagne v. North-*

[11] *United States v. Guerrero-Cortez*, 110 F.3d 647 (8th Cir. 1997) ("We review [Rule 403] evidentiary rulings for an abuse of discretion"); *United States v. Rose*, 104 F.3d 1408, 1413 (1st Cir. 1997) ("Review of the trial court's [Rule 403] evidentiary rulings is for abuse of discretion."); *United Sttaes v. Kizeart*, 102 F.3d 320, 325 (7th Cir. 1996) ("Our court reviews a district court's evidentiary decisions under Rule 403 solely for an abuse of that discretion."); *Pandit v. American Honda Motor Co.*, 82 F.3d 376, 379 (10th Cir. 1996) (appellate court reviews evidentiary rulings for abuse of discretion); *United States v. Karterman*, 60 F.3d 576, 578 (9th Cir. 1995) (Rule 403 and 404(b) evidentiary rulings reviewed for abuse of discretion); *Eiland v. Westinghouse Elec. Corp.*, 58 F.3d 176, 180 (5th Cir.1995) ("[W]e show considerable deference to the district court's [Rule 401 and 403] evidentiary rulings, reviewing them only for abuse of discretion."); *United States v. Boyd*, 53 F.3d 631, 636 (4th Cir. 1995) ("We review a district court's [Rule 401, 402 and 404(b)] evidentiary ruling for an abuse of discretion."); *United States v. Peters*, 15 F.3d 540, 545 (6th Cir. 1994) (Rule 404(b) evidentiary ruling reviewed under an abuse of discretion standard); *Petruzzi's IGA Supermarkets v. Darling-Delaware Co.*, 998 F.2d 1224, 1287 (3d Cir. 1993) ("While ordinarily we review a district court's admissibility rulings under an abuse of discretion standard, when the court's ruling turns on an interpretation of a Federal Rule of Evidence the appropriate standard of review is plenary. [citations omitted] Here, though we do discuss the interpretation of the Rules, at bottom we are using the deferential standard of review because the district court exercised discretion under Rule 403 in excluding the expert testimony"); *United States v. Fortenberry*, 971 F.2d 717, 721 (11th Cir. 1992) ("We review a district court's [Rule 404(b)] evidentiary rulings for abuse of discretion."); *Purnell v. Lord*, 952 F.2d 679, 685 (2d Cir. 1992) ("Evidentiary rulings under Rule 403 are reviewed under an abuse of discretion standard.").

western National Ins. Co., 881 F.2d 309 (6th Cir. 1989) (Sixth Circuit affirmed summary judgment for the defendant employer and stated the trial court did not abuse its discretion in finding irrelevant and overly prejudicial the plaintiff's basis of her claim of age discrimination, *vis*, one isolated comment by her boss).

Like determinations of the admissibility of expert evidence, evidentiary rulings based on Rule 403 involve a trial court's weighing of legal factors as applied to a specific factual context, which often involves credibility and other issues that a trial court is much better situated to analyze than appellate courts. For this reason, appellate courts have historically entrusted evidentiary rulings to the trial court, and will only question such rulings where there is an abuse of discretion or manifest error. This Court has explicitly entrusted Rule 702 analyses to trial courts; it gave trial courts guidance on what standards to utilize; they are best situated to marshal the facts, assess credibility, consider the proffer in the specific context of the case, and apply the law. There is no reason to remove this trust now, and substitute the judgment of a remote appellate court.

E. The Abuse of Discretion Standard Makes Sense As Applied to Trial Court Rulings on Expert Testimony

The *Joiner* court imposed a stricter standard of review on the trial court's exclusion of expert testimony, relying largely on precedent from the Third Circuit. Yet, before the *Daubert* decision, the Eleventh Circuit and the Third Circuit, like other circuits, recognized that an abuse of discretion applied to review of evidentiary rulings. *See, e.g., United States v. McGlory*, 968 F.2d 309, 345 (3d Cir. 1992); *Hancock v. Hobbs*, 967 F.2d 462, 468 (11th Cir. 1992); *Busby v. City of Orlando*, 931 F.2d 764, 784 (11th Cir. 1991); *United States v. Leo*, 941 F.2d 181, 197 (3d Cir. 1991). Why should the standard be changed considering this Court in *Daubert* merely expanded the

criteria for the trial court to consider in determining the reliability of evidence? Reliability has always been required; that is the critical element upon which the admissibility decision is made.

The case law is replete with examples of trial courts carefully considering the reliability of proffered expert testimony before *Daubert*, and admitting it or excluding it based on factors similar to those adopted by this Court later in *Daubert*. For example, Judge Becker in the Third Circuit taught that the abuse of discretion standard is particularly appropriate in reviewing issues related to the admission of expert testimony, where the inquiry involves a balancing test which incorporates important policy elements of Rule 702 and Rule 403. *United States v. Downing*, 753 F.2d 1224, 1240 (3d Cir. 1985). A precursor to *Daubert*, the court outlined a new standard directing the trial court to follow in determining admissibility: preliminary inquiry into the soundness and reliability of the expert's process or technique, consideration of whether the testimony would likely overwhelm, confuse or mislead the jury, and consideration of relevancy. *Id.* This inquiry involves balancing of policies, a task that the trial court is particularly suited to do, regardless that the question of admissibility is a mixed question of law and fact. *Id.*

Before *Daubert*, there was little suggestion that any standard other than abuse of discretion should be used to review the trial court's decisions on admitting expert testimony. *Soden, supra*, 714 F.2d at 502. In *Soden*, the court, using Rule 703 as its foundation, explained that the federal rules require the trial court to examine the reliability of sources for the expert's opinion, even though wide latitude was given to the expert in choosing the sources relied upon. Rule 703 broadened considerably the permissible basis for experts' opinions, which had been limited at common law. *Id.* That, along with the helpful-

ness standard of 702, formed the basis for the notion that the federal rules "liberalized" the rules concerning the admissibility of expert testimony. *See Arcoren, supra; Krist, supra; Bauman, supra; Seese, supra; Merit Motors, supra.* However, while the criteria was broadened, the threshold for reliability was not lowered to permit unreliable evidence to come in at trial. The trial court is indeed best situated to resolve admissibility issues, considering the inquiry into whether reliability has been established must be made on a case by case basis, focusing on the reliability of the opinion and its foundation. *Soden* at 503.

Indeed, the inquiry under Rule 702 and Rule 703 focuses on helpfulness to the jury. That element, which is said to be the touchstone of Rule 702, is the essence of Rule 403. Unless the evidence is reliable, it will not be helpful to the jury. Unless the evidence is reliable, its prejudice outweighs its probative value. The helpfulness requirement, according to Judge Becker, implies "a quantum of reliability" above and beyond "logical relevancy." *Downing, supra*, 753 F.2d at 1240. Accordingly, the trial court must explore the soundness and reliability of the process or technique used by the expert considering factors like those adopted by this Court in *Daubert*. This concept came in part from Judge Weinstein, writing first in 4 J. Weinstein and M. Berger, *Weinstein's Federal Evidence*, ¶ 702[03] (1st ed. 1975) at 702-36 to 702-37, and later in *In re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp. 1223 (E.D.N.Y. 1985). In the latter, Judge Weinstein, like other trial judges before him,[12] carefully

[12] *See In re Swine Flu Immunization Prods. Liab. Litig.*, 538 F. Supp. 567 (D. Colo. 1980); *In re Swine Flu Immunization Prods. Liab. Litig.*, 508 F. Supp. 897 (D. Colo. 1981), *aff'd Lima v. United States*, 708 F.2d 502 (10th Cir. 1983); *Shatkin v. McDonnell Douglas Corp.*, 727 F.2d 202 (2d Cir. 1984) (trial court had discretionary right under Rule 703 to exclude expert testimony which would have hopelessly confused and misled the jury).

examined the underlying basis for an expert's opinion, recognizing full well the ability of expert testimony to overwhelm the jury with that dazzle of apparent expertise which may add confusion, not clarity, to the resolution of the issues. This Court acknowledged that problem in *Daubert*, by citing to Judge Weinstein's discussion of the need to conduct a Rule 403 analysis of proffered expert testimony exploring possible prejudice against probative force. *Daubert* at 595.

In *Daubert*, this Court reaffirmed its confidence in the trial court's ability to undertake the necessary review to determine the reliability, and hence the admissibility of expert testimony. *Daubert* provides a non-exhaustive list of factors to consider and expands the trial court's discretion to consider other factors as may be appropriate to a particular case. The Court reemphasized the need for reliable evidence, entrusting to the gatekeeper the job of admitting only what is reliable and relevant. *Daubert* at 589, 597. It defies logic that the Court would expand the trial court's discretion in making the decision, and then impose a standard of appellate review that gives less deference to the exercise of that discretion. The trial courts proved themselves up to the task pre-*Daubert*. Nothing since should have called their capacity into question.

F. The Proposed "Particularly Stringent" Standard Has No Meaning

The new "particularly stringent" standard of *Joiner* has no meaningful definition. *Joiner* is like other cases which have used a "heightened scrutiny" standard or taken a "hard look" or used a "sharp eye" without defining the parameters to permit generalization to other cases. The words fade into indistinguishable shades of gray, proving little assistance to the courts and the parties. Without an historical basis or good definition for the new *Joiner* standard, appellate courts have little guidance as to how to

apply the standard. Does it lend itself to a result-oriented review? Is the *Joiner* standard at the point where "discretion is a gossamer film, so limp and feeble that appellate judges find no obstacle at all to their contrary views?" Rosenberg, *Judicial Discretion of the Trial Court, Viewed from Above*, 22 Syracuse L. Rev. 635, 651 (1971). If reliability is merely in the "eye of the beholder" the appellate court is invited to step into the shoes of the trial court. For what reason? It is in no better position to make the determination; in fact, the appellate court is hobbled by its inability to consider fully the evidence in the context of the entire case.

G. Multiple Standards Applied to Different Admissibility Factors Unnecessarily Complicates the Review

Some circuits have recently utilized multiple standards of review, dissecting the admissibility decision into hard to isolate components. For example, in *Cook v. American S.S. Co.*, 53 F.3d 733, 738 (6th Cir. 1995), the Sixth Circuit, finding the traditional abuse of discretion standard is "an oversimplification" and "often incorrect," applied three different standards of review to one basic decision: the admissibility of an opinion from an expert.[18]

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[18] The *Cook* Court stated:

> Appellate review of trial court rulings on the admissibility of expert opinion testimony under Fed. R. Evid. 702, depending upon the assignment of error, may involve as many as three separate standards of review. The trial court's preliminary fact-finding under Rule 104(a) is reviewed for clear error. These facts include, but are not limited to, whether the witness's "knowledge, skill, experience, training, or education," Fed. R. Evid. 702, are such as to qualify him or her to testify as an expert at all, and it may include a determination of the tests or experiments that the proffered expert conducted, if any. The court's determination whether the opinion the expert wishes to offer is properly the subject of "scientific, technical, or other specialized knowledge" is a question of law we review de novo . . . . A comparable duty is imposed upon the trial court when the subject of the proposed opinion testimony is

A multiple standard of review is unwieldy when actually put into practice. In fact, later the Sixth Circuit rejected this approach in *United States v. Jones*, 107 F.3d 1147 (6th Cir. 1997). The *Jones* court criticized *Cook's* unnecessary hair splitting, adhering to the abuse of discretion standard for determinations about whether the proffered evidence is scientific knowledge that will assist the trier of fact and the qualification of the witness.

In many cases it is a complex and needlessly onerous task for a court to distinguish precisely between the issue of qualifications, training and experience, reliability and relevance considerations. The *Jones* court explained that, because certain expert testimony "does not always neatly separate itself from whether the particular expert in the case is qualified and whether the testimony will be helpful to the trier of fact, application of a *de novo* standard to this particular prong could be difficult." *Id.* at 1154. Some experts' "experience and training bear a strong correlation to the reliability of the expert's testimony." *Id.* at 1155. Although experience alone does not ensure either reliability or admissibility, it plays enough of a role in the reliability analysis in the context of certain experts "to blur the distinctions between the three separate prongs in *Cook*." *Id.* Thus, the multiple standard approach advocated in *Cook* is difficult to apply to the vast array of expert testimony encountered by courts on a day to day basis. This difficulty was acknowledged in *Petruzzi's IGA Supermarkets, supra,* when the court discussed the multiple intertwined issues which the courts must consider in determining the admission or exclusion of expert evidence. To

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not "scientific" knowledge, but "technical, or other specialized knowledge." Finally, the trial court's determination whether the proffered expert opinion "will assist the trier of fact to understand the evidence or to determine a fact in issue," Fed. R. Evid. 702, is a relevancy determination and therefore one we review for abuse of discretion.

53 F.3d at 788.

dissect the issues, calling one a question of fact or another a question of law fails to recognize how interpendent the prongs of the analysis are. Indeed, a holistic approach to evidence is inherent in the Rules, and is particularly important when considering expert evidence.

The multiple standard approach should also be rejected because it is unnecessary; a singular abuse of discretion standard already addresses that which the multiple standard approach is meant to manage. If a district court incorrectly decides a legal issue during the course of a hearing on the admissibility of expert testimony, then that court has abused its discretion. *See Koon v. United States*, ——U.S.——, 116 S. Ct. 2035, 2047 (1996) ("A district court by definition abuses its discretion when it makes an error of law."); *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 402 (1990) ("An appellate court would be justified in concluding that, in making [legal] errors, the district court abused its discretion.") A *de novo* standard of review is not needed where a trial court commits an error of law.

II. THE HISTORICAL UNDERPINNINGS FOR DEFERENTIAL ABUSE OF DISCRETION STANDARD REMAIN VITAL TODAY

A. Over 100 Years of Precedent For Abuse of Discretion Standard

Since 1892 this Court has respected the exercise of discretion vested in trial courts, overturning a decision only where the exercise of such discretion has been manifestly abused, and there has been a wanton disregard of justice. *Earnshaw v. United States*, 146 U.S. 60, 67-68 (1892). As noted in *Earnshaw*, the general rule is that "some presumption is to be indulged in favor of the propriety and legality" of the exercise of discretion. The same year in *Means v. Bank of Randall*, 146 U.S. 620, 629 (1892), the Court stated that, "The question . . . is one ordinarily

addressed to the sound discretion of the trial court, and in the present case no abuse of that discretion is shown." By 1895 the Court recognized that discretionary actions of the trial court are "not subject to review by this court, unless it be clearly shown that such discretion has been abused"; the Court stated that this concept "is settled by too many authorities to be now open to question." *Isaacs v. United States*, 159 U.S. 487 (1895). Yet, over one hundred years later that concept is being questioned in the context of the admissibility of evidence, an issue falling squarely within the discretion of the court.

As recently as January of this year, this Court recognized that where the trial court is empowered to exercise its discretion, the trial judge should enjoy great deference in such matters, and appellate review of that discretion is the deferential abuse of discretion standard. *Old Chief, supra*, 117 S. Ct. at 647 n.1 (*citing United States v. Abel, supra*, 469 U.S. at 54-55). Different verbal formulas as to what the "abuse of discretion" standard of review requires have been propounded.[14] No matter the formulation, the result is that the reviewing court must accord substantial deference or "great weight" to the district court's judgment.[15]

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[14] Abuse of discretion standard applies when the court bases its judgment on an erroneous view of the law or erroneous assesment of the evidence, *Cooter, supra*, or, is guided by erroneous legal conclusions, *Koon, supra*, or is otherwise "manifestly erroneous." *Salem, supra*, 370 U.S. 31. The theme is lack of reasonableness for the decision: the court's decision is manifestly unreasonable, or exercised on untenable grounds or for untenable reasons, *State ex rel. Carroll v. Junker*, 482 P.2d 775, 784 (Wash. 1971); no reasonable man [or woman] would take the view adopted by the [decision maker], *Lindy Bros. Builders, Inc. v. American Radiator & Standard Sanitary Corp.*, 540 F.2d 102, 115 (3d Cir. 1976); "[n]ot just clearly incorrect, but downright unreasonable." *Fuller v. CBT Corp.*, 905 F.2d 1055, 1058 (7th Cir. 1990).

[15] The "great weight" standard was codified as the "clearly erroneous" standard of Rule 52 when the Federal Rules of Civil Procedure were adopted. K. Kunsch, *Standard of Review (State and Federal): A Primer*, 18 Puget Sound L., Rev. 11, 17 (Fall 1994) (hereinafter, "Kunsch"). See 9A Charles A. Wright & Arthur Miller, *Federal Practice and Procedure*, § 2571 (2d ed. 1994).

No less deference has been afforded when dealing with evidentiary matters than with other discretionary decisions of a trial judge. In such instances the Court looks to the nature of the decision, rather than conducting an analysis of whether a question of fact or law is involved. "A district court is accorded a wide discretion in determining the admissibility of evidence under the Federal Rules." *United States v. Abel, supra*, 469 U.S. at 54. Commensurately, "[t]he standard of review applicable to the evidentiary rulings of the district court is abuse of discretion." *Old Chief, supra*, 117 S. Ct. at 647 n.1 (1997) (finding abuse of discretion under Fed. R. Evid. 403 in the district court's rejection of offer to stipulate to prior conviction, and admitting full record of prior judgment.) As noted above, this same standard of review has been applied to matters of expert evidence. *Salem, supra*, 370 U.S. 31; *Spring, supra*, 99 U.S. at 658 (1879) (receipt or exclusion of expert evidence by trial court will not be reversed unless the ruling is manifestly erroneous).

B. The Rationale For Abuse of Discretion Standard In Evidentiary Matters

The primary reason for the use of a deferential standard of review is the type of decision at issue. This Court has recognized the difficulty in using the legal/factual distinction as the basis for the resulting standard of review. *Cooter & Gell, supra*, 496 U.S. at 401 (1990).[16] If the

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[16] In *Petruzzi's IGA Supermarkets, supra*, the court spoke about the three intertwined reasons for excluding testimony under Rule 702: if the testimony will not assist the trier of fact, if it is not sufficiently reliable, and if the expert lacks qualifications. Those factors have overlapping elements which render them nearly inextricable. To suggest, as the *Joiner* court does, that one is a question of fact and another is a question of law requiring different

question is a mixed question of law and fact, this Court has looked to practical considerations as to whether a deferential or other standard of review will be used. *Ornelas v. United States*, —— U.S. ——, 116 S. Ct. 1657, 1664-65 (1996) (Scalia J., dissenting).

One practicality is "an accommodation of the respective institutional advantages of trial and appellate courts." *Salve Regina College v. Russell*, 499 U.S. 225, 233 (1991). For example, a deferential review of mixed questions of law and fact is warranted when it appears that the district court is "better positioned" than the appellate court to decide the issue in question. *Id.; Miller v. Fenton*, 474 U.S. 104, 114 (1985) ("as a matter of the sound administration of justice, one judicial actor is better positioned than another to decide the issue in question."). Such circumstances include where a district court, "[f]amiliar with the issues and litigants . . . is better situated than the court of appeals to marshal the pertinent facts and apply the fact-dependent legal standard. . . ." *Cooter & Gell, supra*, 496 U.S. at 402; or the trial judge is in a better position to make determinations of credibility, or has, as an inherent result of his role, expertise in making the determination at issue, *Anderson v. Bessemer City*, 470 U.S. 564, 574-75 (1985); or the issue involves supervision of litigation. *See Pierce v. Underwood*, 487 U.S. 552, 558 n.1 (1988).

Deferential review is warranted when "probing appellate scrutiny will not contribute to the clarity of legal doctrine." *Salve, supra*, 499 U.S. at 233; *Miller v. Fenton, supra*, 474 U.S. at 114; *see also Cooter & Gell, supra*, 496 at 402. Clarification of the law requires generalization. As this Court recognized, "[o]ne of the 'good' reasons for conferring discretion on the trial judge is the sheer impracticability of formulating a rule of decision for the matter in

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standards of review, demonstrates the futility of the exercise, and the reason abuse of discretion is the appropriate standard of review.

issue." *Pierce, supra*, 487 U.S. at 561 (*quoting* Rosenberg, *Judicial Discretion of the Trial Court, Viewed from Above*, 22 Syracuse L. Rev. 635, 662-663 (1971). Deference to the district court is due where the matter is "precisely such a multifarious and novel question, little susceptible, . . . of useful generalization, and likely to profit from the experience that an abuse-of-discretion rule will permit to develop." *Id.* at 562.

The efficient allocation of judicial resources is also important. "The abuse of discretion standard acknowledges that appellate courts in general, and this Court in particular, should not expend their limited resources making determinations that can profitably be made only at the trial level." *Wayte v. United States*, 470 U.S. 598, 624-25 (1985) (Marshall, J., Brennan, J., dissenting). Deference is due to the trial court where even if the appellate court can acquire the district judge's full knowledge of the factual setting, such acquisition will come at unusual expense of substantial judicial time and resources. *Pierce, supra.* This is true particularly where "[d]uplication of the trial judges' efforts in the court of appeals would very likely contribute only negligibly to the accuracy of fact determination at a huge cost in diversion of judicial resources." *Anderson, supra*, 470 U.S. at 574-575.

Further, there is the issue of finality, and the effect of the choice of standard of review on the appellate dockets. "The more deference given to the decision of the lower tribunal, the less likely the losing party is to appeal that decision. Regardless of the outcome, parties will at least have the satisfaction of knowing that the issue has been determined and they can move on with their lives." Kunsch, at 19-20. As noted in *Cooter & Gell*, 496 U.S. 384 at 404:

> [D]eference will streamline the litigation process by freeing appellate courts from the duty of reweighing evidence and reconsidering facts already weighed

and considered by the district court; it will also discourage litigants from pursuing marginal appeals, thus reducing the amount of satellite litigation.

Each and every reason for application of a deferential standard of review applies to trial court decisions on the admissibility of expert evidence. They apply with as much force when the trial court is challenged for excluding the evidence as when it is challenged for admitting it.

CONCLUSION

This court should reaffirm the deferential abuse of discretion standard for review of all trial court rulings concerning the admissibility of expert testimony, regardless of the result of the ruling. This case should be remanded to the Eleventh Circuit for reconsideration and application of the abuse of discretion standard to the issues presented.

Respectfully submitted,

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APPENDIX

APPENDIX

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American Automobile Manufacturers Assn.
American Brands, Inc.
American Home Products Corporation
American Suzuki Motor Corporation
Andersen Corporation
Anheuser-Busch Companies
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Atlantic Richfield Company
BASF Corporation
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Becton-Dickinson & Company
Beech Aircraft Corporation
BIC Corporation
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Dow Chemical Company, The
Eaton Corporation
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Hocchst Marion Roussel, Inc.
Honda North America, Inc.

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International Paper Company
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Westinghouse Electric Corporation
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No. 96-188

IN THE
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OCTOBER TERM, 1996

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Petitioners,

v.

ROBERT K. JOINER, *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Eleventh Circuit

BRIEF OF AMICUS CURIAE THE WASHINGTON LEGAL FOUNDATION IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Amicus will address the following question:

Whether district court decisions regarding the admissibility of expert testimony should be reviewed under the traditional abuse of discretion standard applied to evidentiary decisions.

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IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1996

No. 96-188

GENERAL ELECTRIC COMPANY, *et al.*
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v.

ROBERT K. JOINER, *et al.*
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Eleventh Circuit

BRIEF OF AMICUS CURIAE THE WASHINGTON LEGAL FOUNDATION IN SUPPORT OF PETITIONERS

INTEREST OF AMICUS CURIAE[1]

The Washington Legal Foundation ("WLF") is a non-profit public interest law and policy center based in

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[1] Pursuant to Supreme Court Rule 37.6, amicus hereby indicates that no counsel for a party in this case authored this amicus brief in whole or in part.

Washington, D.C., with supporters nationwide. WLF regularly appears before federal and state courts promoting economic liberty, free enterprise principles, and a limited and accountable government. WLF's Legal Studies Division also publishes monographs and other publications on these topics.

In particular, WLF has devoted substantial resources over the years through litigation and publishing to promote civil justice reform, including tort reform. WLF appeared as an amicus curiae in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its Legal Studies Division published a monograph on the subject. Charrow, "Scientific Evidence In The Courtroom: Admissibility And Statistical Significance After *Daubert*" (1994).

WLF believes that it can bring a broader perspective on the issues presented in this case, which will assist this Court in deciding this case in such a way as to give clearer guidance to appellate courts reviewing admissibility decisions regarding expert evidence. By letters filed with the Clerk of the Court, the parties have consented to the filing of this brief.

STATEMENT OF THE CASE

Amicus curiae is, in the interest of brevity, omitting any detailed statement of the facts in this case. Amicus curiae adopts by reference the statement of facts contained in Petitioners' Brief.

In brief, Respondents, an electrician and his wife, sued Petitioners in state court in Georgia, claiming that the

husband's lung cancer (he had smoked for eight years) had been "promoted" by exposure to polychlorinated biphenyls ("PCBs"), furans, and dioxins in transformers manufactured by Petitioners General Electric and Westinghouse. The suit was removed to the United States District Court for the Northern District of Georgia.

In connection with the Petitioners' motion for summary judgment, the District Court reviewed in detail the scientific opinions of Respondents' experts and the methodologies they employed to reach those opinions. The District Court concluded that although there was a scientific basis for opining that there had been exposure to PCBs (but not furans or dioxins), the Respondents' experts had presented no scientific support on causation and, therefore, their opinions did not rise above "subjective belief or unsupported speculation." *Joiner v. General Elec. Co.*, 864 F. Supp. 1310, 1325 (N.D. Ga. 1994). Accordingly, the District Court, citing this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), excluded the Respondents' proffered expert testimony on causation under Rule 702 of the Federal Rules of Evidence. Given the plaintiffs' failure to produce admissible scientific evidence of causation, the District Court granted summary judgment for the Petitioners. 864 F. Supp. at 1326.

Splitting 2-1 and issuing three separate opinions, the Court of Appeals for the Eleventh Circuit reversed. *Joiner* v. *General Elec. Co.*, 78 F.3d 524 (11th Cir. 1996). The judges disagreed as to the proper standard and nature of appellate review of district court rulings under *Daubert*.

Judge Rosemary Barkett, writing for the majority, recognized that district court rulings on admissibility are

ordinarily "reviewed for abuse of discretion." *Id.* at 529. Nevertheless, Judge Barkett applied what she characterized as "a particularly stringent standard of review to the trial judge's exclusion of expert testimony," because the Federal Rules of Evidence display a preference for admissibility, and cited as authority this Court's decision in *Daubert* and the Third Circuit's opinion in *In re Paoli R.R. Yard PCB Litigation*, 35 F. 3d 717, 750 (3d Cir. 1994), *cert. denied sub nom. General Elec. Co. v. Ingram*, ___ U.S. ___, 115 S.Ct. 1253 (1995). *See* 78 F.2d at 529. Using this "particularly stringent standard of review," the majority conducted its own examination of the opinions of the two experts and concluded that the District Court had "improperly assessed the admissibility of the proffered scientific expert testimony." *Id.* at 528. The majority rebuked the District Court for examining whether there was support in science for each link in the reasoning leading to the experts' conclusions, concluding that the District Court should have accepted the conclusions "viewed in their entirety." *Id.* at 532. Reexamining the entire record, including materials not cited by any party in the District Court, the Court of Appeals held that "the testimony of plaintiffs' experts was erroneously excluded," and reversed. *Id.* at 534.

Judge Edward S. Smith, Senior U.S. Circuit Court Judge for the Federal Circuit and sitting by designation, dissented, specifically disagreeing with the majority's holding as to the standard of appellate review. *Id.* at 536. Citing many decisions from other Circuits, the dissent concluded that "[i]n applying the Daubert framework, the trial court's ruling on whether the expert opinion is (1) reliable . . . and (2) relevant . . . is reviewed for abuse of discretion." *Id.* "Those circuits addressing Daubert" he

found, give "deference to the trial court's admissibility determinations." *Id.*, n.1 (citations omitted). The dissent indicated that the trial court's `gatekeeper' function requires broad discretion. Accordingly, "[w]e should not require the trier of fact to accept blindly the expert's word to fill the analytical gap between proffered `scientific knowledge' and the expert's conclusion." *Id.* at 535. Approving "the trial court's step-by-step approach," *id.* at 540, the dissent stated that:

> [S]ifting through the expert's testimony is a crucial "gatekeeping" function that not only requires the trial court to decide which experts may testify, but also requires the trial court to decide what the experts may testify about (i.e., the trial court must separate the wheat from the chaff). . . . [A]n expert may not bombard the court with innumerable studies and then, with smoke and sleight of hand, leap to the conclusion.
>
> * * * *
>
> [I]f the trial court finds the expert testimony requires too great a leap of faith across the analytical gap, it may properly request good grounds to bridge the gap before admitting the testimony. . . . This is not too onerous a request.

Id. at 537, 539 (citations omitted). The dissent concluded that "[t]he trial court properly applied Daubert and did not abuse its discretion in ruling certain expert testimony inadmissible." *Id.* at 540. The Petitioners' request for rehearing and rehearing *en banc* were denied.

SUMMARY OF ARGUMENT

District court decisions regarding the admissibility of expert testimony should be reviewed under the same abuse of discretion standard historically applied to all other evidentiary rulings. Because each case presents to the court different facts and issues, the district court, as the gatekeeper of evidence, is uniquely situated to evaluate proffered expert testimony to determine whether it is scientific and, if so, whether it is useful to the trier of fact and relevant to the issues being litigated. Neither the adoption of the Federal Rules of Evidence in 1975, nor this Court's ruling in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), signaled a need to depart from the abuse of discretion standard that appellate courts have traditionally applied when reviewing the evidentiary rulings of trial courts.

The district court's evidentiary gatekeeping role, which *Daubert* firmly established, mandates the broad discretion afforded their evidentiary decisions. In order to apply the applicable evidentiary framework regarding expert testimony to the unique facts and circumstances of each case, district courts must invest a significant amount of time reviewing the record to understand the scientific evidence presented by the experts and the methodologies they employ to reach their opinions. The district courts spend an equal amount of time parsing through the allegations of the parties in order to determine whether the scientific evidence is relevant to issues in a case. Accordingly, district court decisions regarding the admissibility of scientific evidence should only be reversed if the district court abused its discretion by reaching a "clearly erroneous" result.

Moreover, this standard of review should apply regardless of what stage of the proceeding the evidentiary determination is made. Having lived with the case from its inception, and having overseen the day-to-day development of the action through pre-trial conferences, pre-trial rulings, and supervision of discovery, the district courts are in a far better position to evaluate the evidence that is presented than appellate courts reviewing a cold record. Indeed, it would be a tremendous waste of judicial resources and contrary to our legal system's policy of resolving disputes finally and quickly to treat a district court's evidentiary decisions on a dispositive motion as a mere rehearsal for later appellate review.

ARGUMENT

I. TRIAL COURT DECISIONS REGARDING THE ADMISSIBILITY OF PROFFERED SCIENTIFIC EVIDENCE SHOULD BE GIVEN SIGNIFICANT DEFERENCE

A. Historical Standard Of Review On Evidentiary Rulings

A district court's evidentiary decisions have traditionally been reviewed by this Court[2] and in all of the

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[2] *See, e.g., Stillwell & Bierce Mfg. Co. v. Phelps*, 130 U.S. 520, 527 (1889); *Congress & Empire Spring Co. v. Edgar*, 99 U.S. 645, 658 (1878); *Salem v. U.S. Lines Co.*, 370 U.S. 31, 35 (1962); *Hamling v. United States*, 418 U.S. 87, 108 (1974).

federal circuits for abuse of discretion.[3] The reason for this is twofold. First, it is impractical to formulate an evidentiary rule to cover each and every situation that could arise in a proceeding, given the "'multifarious, fleeting, special, narrow facts that utterly resist generalization.'" *See* 19 *Moore's Fed'l Practice* § 206.05[1] (1997) (quoting Rosenberg, "Judicial Discretion of the Trial Court, Viewed from Above," 22 SYRACUSE L. REV. 635, 662 (1971)).

Second, evidentiary decisions involve a balancing of a variety of factors, including, but certainly not limited to, the usefulness, reliability and relevance of the proffered information. Because no two lawsuits are identical, district courts are uniquely situated to evaluate the context and circumstances of the proffered evidence to determine the need for its admissibility in a particular case.

Indeed, under the common law, courts have long recognized the discretion that should be afforded a trial

[3] *See, e.g., Mitchell v. Dupnik*, 75 F.3d 517, 527 (9th Cir. 1996); *Boughton v. Cotter Corp.*, 65 F.3d 823, 831 (10th Cir. 1995); *Affiliated Mfrs., Inc. v. Aluminum Co. of America*, 56 F.3d 521, 525 (3d Cir. 1995); *Walker v. NationsBank of Florida N.A.*, 53 F.3d 1548, 1554 (11th Cir. 1995); *O'Dell v. Hercules, Inc.*, 904 F.2d 1194, 1200 (8th Cir. 1990); *Fisher v. Vassar College*, 70 F.3d 1420, 1445 (2d Cir. 1995); *Buckner v. Sam's Club, Inc.*, 75 F.3d 290, 292 (7th Cir. 1996); *Kelly v. Boeing Petroleum Serv., Inc.*, 61 F.3d 350, 356 (5th Cir. 1995); *Carter v. Ball*, 33 F.3d 450, 456 (4th Cir. 1994); *Bath & Body Works, Inc. v. Luzier Personalized Cosmetics, Inc.*, 76 F.3d 743, 750 (6th Cir. 1996); *Blinzer v. Marriott Int'l, Inc.*, 81 F.3d 1148, 1158 (1st Cir. 1996); *Carey Canada, Inc. v. Columbia Cas. Co.*, 940 F.2d 1548, 1559 (D.C. Cir. 1991); *Munoz v. Strahm Farms, Inc.*, 69 F.3d 501, 503 (Fed. Cir. 1995).

court's evidentiary decisions. As early as 1894, in *Vaughan v. State*, the Arkansas Supreme Court stated:

> [T]he trial court had a discretion [to make the evidentiary decision], which was only limited to the extent it should not be abused. It is absolutely essential that circuit courts be vested with such discretion. The judge is acquainted with the surroundings, sees and hears the witnesses, and is *the one* to be satisfied as to whether the conditions exist. . . . [W]e will not review [the trial judge's] discretion to disturb his findings upon the facts before
> him.

58 Ark. 353, 24 S.W. 885, 890 (1894), *quoted in* I. *Wigmore on Evidence* (Tiller's rev.), § 16 at 757 (emphasis in original).[4]

[4] This reasoning has reverberated in decisions throughout the years. *See, e.g., Lee v. Suess*, 318 S.C. 283, 285, 457 S.E.2d 344, 345 (1995); *In re Interest of M.L.S.*, 234 Neb. 570, 571, 452 N.W.2d 39, 40 (1990); *Mitchell v. Commonwealth*, 908 S.W.2d 100, 102 (Ky. 1995); *Kealoha v. County of Hawaii*, 74 Haw. 308, 309, 844 P.2d 670, 671 (1993); *Morasso v. State*, 74 Fla. 269, 274, 76 So. 777, 779 (1917); *Kinsey v. Pacific Mut. Life Ins. Co.*, 178 Cal. 153, 156, 172 P. 1098, 1099 (1918); *Vallejo & N.R. Co. v. Reed Orchard Co.*, 169 Cal. 545, 147 P. 238 (1915); *Hardesty v. People*, 52 Colo. 450, 121 P. 1023 (1912); *Brooke v. People*, 23 Colo. 375, 48 P. 502 (1897); *City of Chicago v. Mullin*, 285 Ill. 296, 120 N.E. 785 (1918); *Commonwealth v. Coyne*, 228 Mass. 269, 117 N.E. 337 (1917).

This Court has applied this highly deferential standard of review to decisions regarding admissibility of witness testimony from experts dating at least as far back as 1878. For example, in *Congress & Empire Spring Co. v. Edgar*, 99 U.S. 645 (1878), this Court stated:

> Whether a witness is shown to be qualified or not as an expert is a preliminary question to be determined in the first place by the court . . . . Cases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous.

99 U.S. at 658 (citations omitted). Subsequent cases echoed this holding on the deference trial judges' expert evidentiary decisions are to receive.[5]

In *Salem v. U.S. Lines Co.*, 370 U.S. 31 (1962), this Court reiterated the deference to be accorded the trial court's rulings on the admissibility or inadmissibility of expert testimony. Specifically, the Court stated that, "the trial judge has broad discretion in the matter of the

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[5] *See, e.g., Stillwell & Bierce Mfg. Co. v. Phelps*, 130 U.S. 520, 527 (1889); *Montana Ry. Co. v. Warren*, 137 U.S. 348, 353 (1890); *Chateaugay Ore & Iron Co. v. Blake*, 144 U.S. 476, 484 (1892); *Gila Valley, Globe & N. Ry. Co. v. Lyon*, 203 U.S. 465, 475 (1906); *Chicago Great W. Ry. Co. v. McDonough*, 161 F. 657, 662 (1908); *U.S. Smelting Co. v. Parry*, 166 F. 407, 414 (1909); *Hines v. Consolidated Rail Corp.*, 926 F.2d 262, 265 (3d Cir. 1991); *United States v. Welch*, 945 F.2d 1378, 1381 (7th Cir. 1991), *cert. denied*, 502 U.S. 118 (1992).

admission or exclusion of expert evidence, and his action is to be sustained unless manifestly erroneous." *Id.* at 35 (citation omitted). Indeed, "[b]ecause gauging an expert witness's usefulness is almost always a case-specific inquiry, the law affords trial judges substantial discretion in connection with the admission or exclusion of opinion evidence." *United States v. Sepulveda*, 15 F.3d 1161, 1183 (1st Cir. 1993), *cert. denied*, 512 U.S. 1223 (1994).[6]

B. The Federal Rules Of Evidence Provide District Courts Broad Discretion To Make Evidentiary Decisions, Including Decisions Involving Expert Testimony

Prior to 1975, the admissibility of evidence in general and expert testimony in particular was governed by the common law. In 1975, Congress, with input from the legal community, enacted the Federal Rules of Evidence ("FRE"), which established guidelines and general requirements regarding the admissibility of evidence. By their nature, the FRE continue the tradition of providing the trial courts with

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[6] The Hon. Jack B. Weinstein, United States District Court Judge for the Eastern District of New York, posits (in reference to Rule 403, regarding exclusion of probative expert testimony based on its prejudicial effect), "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge. . . exercises more control over experts than over lay witnesses." Weinstein, *Rule 702 of the Federal Rules of Evidence Is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 632 (1991).

broad discretion to make decisions regarding the admissibility or inadmissibility of evidence.[7]

For instance, under FRE 403 the district court judge must assess the evidence to determine if the probative value of the evidence is "substantially outweighed" by the potential prejudice, confusion, or undue delay. This standard requires the district court to balance a number of factors, including the issues in the case, the allegations of the parties and the nature and quality of the evidence. As a result, such evidentiary rulings have been accorded significant deference by appellate courts.[8]

The same is true under FRE 401 and 402, where the district court judge must ensure that the evidence admitted is relevant, which, again, requires the district court to have an in-depth understanding of the particular facts and circumstances of a case in order to exercise its discretion, as there is no hard and fast rule by which relevancy is determined. Thus, a district court's decision to admit or

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[7] *See Federal Rules of Evidence: Hearings Before the Senate Comm. on the Judiciary*, 93 Cong., 2d Sess. 206 (1974) (Testimony of Albert Jenner, Jr., Chairman of the Advisory Committee) ("[W]e could see that [allowing] discretion to be exercised by a judge is preferable to hardening a rule of evidence, to etching it in granite. We always operated, Mr. Chairman, to afford the U.S. district judges wise discretion with respect to the admission or exclusion of evidence.").

[8] *See, e.g., Construction, Ltd. v. Brooks-Skinner Bldg. Co.*, 488 F.2d 427, 431 (3d Cir. 1973) ("The task of assessing potential prejudice is one for which the trial judge, considering his familiarity with the full array of evidence in a case, is particularly suited.").

exclude evidence on the basis of relevance has also consistently been reviewed by appellate courts under an abuse of discretion standard.[9]

FRE 702, which governs the admissibility of expert scientific evidence, also requires trial courts to exercise considerable discretion. This is because FRE 702 sets forth guiding principles regarding the admissibility of scientific evidence by a qualified expert; it does not, however, provide a bright line test for rendering such determinations. Thus, before proceeding, the district judge must first determine if the witness is qualified as an expert by knowledge, skill, experience, training or education, and then, if the witness is deemed qualified, the district judge must further decide whether the scientific, technical or other specialized knowledge the expert provides will assist the trier of fact to understand the evidence or to determine a fact in issue. *See* FRE 702. Of necessity, this requires the district court to invest significant time and resources in

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[9] *See, e.g., United States v. Garr*, 461 F.2d 487, 489 (5th Cir.), *cert. denied*, 409 U.S. 880 (1972); *United States v. Ashley*, 555 F.2d 462, 465 (5th Cir.), *cert. denied*, 434 U.S. 869 (1977). Courts have also consistently applied this abuse of discretion standard when reviewing other evidentiary rulings under the FRE. *See, e.g., Horne v. Owens-Corning Fiberglas*, 4 F.3d 276, 282 (4th Cir. 1993) (review admissibility of evidence under FRE 804(b)(1) under an abuse of discretion standard); *United States v. Duran*, 4 F.3d 800, 803 (9th Cir. 1993), *cert. denied*, 510 U.S. 1078 (1994) (reviewing in-court identification testimony under FRE 901(a) and voice identifications under FRE 901(b)(5) under an abuse of discretion standard); *Trans Union Credit Infor. v. Associated Credit Serv., Inc.*, 805 F.2d 188, 192 (6th Cir. 1986) (review of district court's evidentiary ruling under FRE 408 regarding statements made in furtherance of settlement is clearly erroneous).

reviewing the scientific and technical evidence presented by the parties so that it can determine whether such evidence is reliable and whether it is relevant to the issues in the case.

Because such determinations must be made based on general guidelines, not specific rules, and require extensive factual development by the district court, they should be accorded the same deference given district court rulings regarding the relevance, reliability and potential prejudicial effect of evidence. Indeed, there is nothing in the legislative history of the FRE to suggest that a trial court's decisions regarding scientific expert evidence should be treated any differently by an appellate court than any other evidentiary ruling.[10]

C. The Teachings Of *Daubert* Compel A Continued Abuse Of Discretion Standard Of Review For Evidentiary Decisions Involving Expert Evidence

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), this Court held that FRE 702 superseded the *Frye* standard as to admissibility of scientific evidence.[11]

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[10] In fact, Rule 702 received little attention during the drafting and enactment process. The Rule was revised only slightly by its drafters; the phrase, "in the form of an opinion or otherwise" was added to the end of the provision to clarify that experts may testify to facts and relevant data in addition to an opinion. *See* Advisory Committee's Note, Rule 702. Similarly, the Rule generated no debate on the floor of Congress, where it was enacted without amendment. *See* 120 Cong. Rec. 2382 (Feb. 6, 1974).

[11] After its enactment, courts, while applying FRE 702, (continued...)

Specifically, a district court should admit into evidence scientific testimony offered by a qualified expert if such evidence will assist the trier of fact to understand the evidence or to determine a fact in issue. While clarifying the standard for admissibility, this Court explained:

> That the Frye test was displaced by the Rules of Evidence does not mean . . . that the Rules themselves place no limits on the admissibility of purportedly scientific testimony or evidence. Nor is the trial judge disabled from screening such evidence. To the contrary, under the Rules the trial judge must ensure that any and all scientific evidence admitted is not only relevant, but reliable.

509 U.S. at 589 and n.7. This Court went on to restate the two-prong test which must be satisfied in order for such expert testimony to be admitted under the FRE: (1) the expert testimony must be "scientific knowledge," *i.e.*, supported by appropriate validation; *and* (2) the evidence or testimony must assist the trier of fact to understand the evidence or to determine a fact in issue. *Id.* at 592.

In determining whether the expert evidence consists of "scientific knowledge," *Daubert* directs district courts to consider several non-exhaustive factors, including: (1) whether the theory or methodology used by the expert can be, and has been, tested; (2) whether the theory or

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[11](...continued)
continued to rely on the common law standard announced in *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923), which allowed such evidence to be admitted if it was "generally accepted" in the field.

methodology has been subjected to peer review and publication; (3) the known or potential rate of error of the method used; and (4) the degree of acceptance within the relevant scientific community. *Id.* at 593-94. Furthermore, in addition to determining whether the evidence will, in fact, be helpful to the trier of fact, the Court warned district court judges to pay heed to other evidentiary rules, including Rule 403, which allows district courts to exclude relevant evidence on the grounds of prejudice, confusion or waste of time.

Daubert, thus, instructs the district courts to make case-specific decisions regarding the admissibility of expert testimony, which will vary significantly depending on the facts, circumstances and issues of the particular case. In fact, *Daubert's* designation of the district courts as the evidentiary "gatekeepers" delegates to the district courts significant latitude to undertake the requisite evidentiary evaluation. Accordingly, just as district courts are afforded great discretion under evidentiary rules like FRE 401 and 403, district court decisions under FRE 702 should be afforded the same discretion and reviewed under the same abuse of discretion standard.

Moreover, although *Daubert* held that FRE 702 displaced the common law *Frye* standard regarding the conditions under which expert testimony should be admitted, *Daubert* did not counsel that expert evidentiary decisions required a heightened standard of review from that applied at common law. Indeed, as the *Daubert* decision recognized, common law should continue to serve as an aid to the application of the FRE, and a "'source of guidance in

the exercise of delegated powers.'"[12] Where a common law precept is entirely consistent with a Rule's general requirement of admissibility, that common law rule should be applied.[13] Accordingly, because the longstanding common law standard of review for expert evidentiary decisions -- abuse of discretion, *see supra* at 10-11 -- is entirely consistent with the broad discretion afforded a district court under FRE 702 in making expert evidentiary

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[12] 509 U.S. at 588 (quoting *United States v. Abel*, 469 U.S. 45, 51-52 (1984)). The *Abel* case concerned whether, under the Rules, it is permissible to impeach a witness for bias. The Court noted the unanimity of approach regarding impeachment in the courts, as well as the concept's conformity with the Rules, in holding that the doctrine of impeachment survived. 469 U.S. at 50-52.

[13] *United States v. Abel*, 469 U.S. 45, 51-52 (1984). *See also Bourjaily v. United States*, 483 U.S. 171 (1987). In *Bourjaily*, the court held that in determining preliminary facts relevant to Rule 801(d)(2)(E), there was no requirement that courts look only to independent evidence other than hearsay statements sought to be admitted. To the extent that its prior cases had indicated that courts could not look to the hearsay statements for any purpose, they had been superseded by Rule 104(a), which provides that, in determining preliminary admissibility questions the court "is not bound by the rules of evidence."

Bourjaily is instructive for yet another reason. The Court also held that the traditional, common law requirement that the standard of proof for preliminary questions concerning the admissibility of evidence (a preponderance of proof) survived, given that the Rules did not define the standard of proof that should apply. *Id.* at 175-76. A similar argument exists regarding the standard of review in this case. Because the FRE does not define the standard of review applicable to evidentiary decisions, courts should continue to apply the common law standard of abuse of discretion.

decisions, it should continue to be the applicable review standard for evidentiary decisions involving expert evidence.

II. THE ABUSE OF DISCRETION REVIEW STANDARD SHOULD APPLY REGARDLESS OF THE STAGE OF THE PROCEEDINGS IN WHICH THE EVIDENTIARY DETERMINATIONS ARE MADE

The fact that a district court's decision to exclude expert evidence pursuant to *Daubert* results in the granting of summary judgment should not alter the standard of review applied to the district court's evidentiary ruling. A district court's evidentiary decisions should be afforded broad discretion no matter what stage of the proceedings such rulings are made.[14] Thus, when the district court considers the evidence proffered in support of or in opposition to a motion for summary judgment,[15] its decisions with respect

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[14] *See, e.g., Cortes-Irizarry v. Corporacion Insular De Seguros*, 111 F.3d 184, 188 (1st Cir. 1997) ("The plaintiff posits that Daubert is strictly a time-of-trial phenomenon. She is wrong. The Daubert regime can play a role during the summary judgment phase of civil litigation. If proffered expert testimony fails to cross Daubert's threshold for admissibility, a district court may exclude that evidence from consideration when passing upon a motion for summary judgment.") (citations omitted); *First United Fin. Corp. v. U.S. Fidelity & Guar. Co.*, 96 F.3d 135, 136-37 (5th Cir. 1996) ("The admissibility of expert testimony is governed by the same rules, whether at trial or on summary judgment. And we review the decision of the trial court by the same abuse of discretion standard.") (citation omitted).

[15] It is well-established that "[w]hen deciding a motion for (continued...)

to admissibility of evidence should be given deference, and only its legal determinations as to the grant or denial of summary judgment based on the admissible evidence should be reviewed *de novo*. *See, e.g., Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1109 (5th Cir. 1991) (*en banc*), *cert. denied*, 503 U.S. 912 (1992).[16]

As a matter of the sound administration of justice, deference is "owed to the 'judicial actor . . . better positioned than another to decide the issue in question.'" *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 403 (1990) (citations omitted). Advocating a standard whereby an appellate court would be required to re-examine scientific evidence proffered to the district court under a *de novo* standard of review, thereby disregarding the significant time and effort expended by the district court in making its evidentiary determinations, merely because the district court granted summary judgment, would be nothing short of a waste of judicial resources. The rationale that, under those circumstances, an appellate court can review a "cold record" grossly undervalues the trial court's first-hand knowledge and feel for the case. *See, e.g.*, 19 *Moore's Federal*

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[15](...continued)
summary judgment, only admissible evidence may be considered." *B.F. Goodrich v. Betkoski*, 99 F.3d 505, 525 (2d Cir. 1996) (citations omitted).

[16] *See also* Childress, *A 1995 Primer on Standards of Review in Federal Civil Appeals*, 161 F.R.D. 123, 142 (1995) ("Although review over the overall [summary judgment] decision is de novo, some rulings on admissibility of evidence underlying the summary judgment decision may receive 'manifest error' deference.") (citation omitted).

Practice, § 206.05[1] at 206-29 (1997) (abuse of discretion standard "is deferential to the district court's familiarity with the proceedings and evidence in the case").

Through their roles in discovery, court conferences and interaction with counsel, district court judges are in the best position to review scientific evidence and have a distinct advantage over the appellate court in evaluating scientific evidence that is proffered in conjunction with a motion for summary judgment. Regarding these important, yet intangible aspects, this Court has noted:

> By reason of settlement conferences and other pre-trial activities, the district court may have insights not conveyed by the record, into such matters as whether particular evidence was worthy of being relied upon . . . . Moreover, even where the district judge's full knowledge of the factual setting can be acquired by the appellate court, that acquisition will often come at unusual expense, requiring the court to undertake the unaccustomed task of reviewing the entire record, not just to determine whether there existed the usual minimum support for the merits determination made by the factfinder below, but to determine whether urging of the opposite merits determination was substantially justified.

Pierce v. Underwood, 487 U.S. 552, 560 (1988).

Indeed, the two-level review of the district court's evidentiary findings and application of legal standards for dispositive motions is similar to the two-level review of the district court's factual findings and application of legal

standards in a bench trial. While the legal determinations made by the district court are reviewed *de novo*, great discretion is afforded to its factual determinations. *See* Fed. R. Civ. P. 52.

Prior to 1985, Rule 52(a) simply provided that the district court's findings of fact would not be set aside unless clearly erroneous. Some circuit courts determined that, when such factual findings did not rest on demeanor evidence and evaluation of a witness' credibility, there was no reason to defer to the trial court because the appellate court was in as good a position to review a purely documentary record. *See, e.g., Atari, Inc. v. North American Philips Consumer Elec. Corp.*, 672 F.2d 607, 614 (7th Cir.), *cert. denied*, 459 U.S. 880 (1982); *Marcum v. United States*, 621 F.2d 142, 144-45 (5th Cir. 1980). However, other circuit courts applied the "clearly erroneous" standard even when the trial court's findings were based solely on documentary evidence or on inferences from undisputed facts. *See, e.g., Maxwell v. Sumner*, 673 F.2d 1031, 1036 (9th Cir.), *cert. denied*, 459 U.S. 976 (1982); *United States v. Texas Educ. Agency*, 647 F.2d 504, 506-07 (5th Cir. 1981), *cert. denied sub nom. South Park Indep. School Dist. v. United States*, 454 U.S. 1143 (1982).

To resolve this dispute, Rule 52(a) of the Federal Rules of Civil Procedure was amended in 1985 to make clear that a trial court's factual determinations, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous. Particularly instructive is the advisory committee's notes explaining the rationale for this amendment:

The principal argument advanced in favor of a more searching appellate review of findings by the district court based solely on documentary evidence is that the rationale of Rule 52(a) does not apply when the findings do not rest on the trial court's assessment of credibility of the witnesses but on an evaluation of documentary proof and the drawing of inferences from it, thus eliminating the need for any special deference to the trial court's findings. These considerations are outweighed by the public interest in the stability and judicial economy that would be promoted by recognizing that the trial court, not the appellate tribunal, should be the finder of the facts. To permit courts of appeals to share more actively in the fact-finding function would tend to undermine the legitimacy of the district courts in the eyes of litigants, multiply appeals by encouraging appellate retrial of some factual issues, and needlessly reallocate judicial authority.

Fed. R. Civ. P. 52 advisory committee's note.

This reasoning is equally applicable to a trial court's expert evidentiary decisions in connection with dispositive motions. In performing their *Daubert* gatekeeping functions, district courts will have expended significant judicial resources in reviewing the scientific evidence proffered by the parties to determine its validity and application to the peculiar facts and circumstances of a particular case. Affording the losing party an opportunity to completely retry its case to an appellate court would not only needlessly waste the resources of the appellate courts and the parties, but it would also impede the goal of a final

and quick resolution since the appellate court will invariably need to trudge through factual arguments previously evaluated by the trial court. Moreover, the rationale for deferring to a trial court's factual findings

> is not limited to the superiority of the trial judge's position to make determinations of credibility. The trial judge's major role is the determination of fact, and with experience in fulfilling that role comes expertise. Duplication of the trial judge's efforts in the court of appeals would very likely contribute only negligibly to the accuracy of fact determination at a huge cost in diversion of judicial resources. In addition, the parties to a case on appeal have already been forced to concentrate their energies and resources on persuading the trial judge that their account of the facts is the correct one; requiring them to persuade three more judges at the appellate level is requiring too much. As the Court has stated in a different context, the trial on the merits should be "the 'main event' . . . rather than a 'tryout on the road.'"

Anderson v. Bessemer City, 470 U.S. 564, 574-75 (1985) (citing *Wainwright v. Sykes*, 433 U.S. 72, 90, 97 (1977)).

CONCLUSION

Fact-specific determinations regarding the admissibility of expert evidence are best left to the discretion of the district court. Indeed, the district court's application of the *Daubert* framework affords the district court a feel for the evidence not available to the appellate court. Thus, given this Court's expressed confidence in the ability of district

court judges to undertake the fact-driven review necessary to rule on the admissibility of scientific evidence, *Daubert*, 509 U.S. at 593, the district court's determinations on admissibility of expert decisions should be reviewed under an abuse of discretion standard. Accordingly, amicus curiae respectfully requests that the judgment of the court of appeals be reversed and the case remanded.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY, *ET AL.*,
Petitioners,

v.

ROBERT K. JOINER, *ET AL.*,
Respondents.

**On Writ of Certiorari
to the United States Court of Appeals
for the Eleventh Circuit**

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

What is the standard for appellate review of district court decisions excluding purported expert testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY, *ET AL.*,
Petitioners,

v.

ROBERT K. JOINER, *ET AL.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTEREST OF THE *AMICUS CURIAE* [1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the country's leading research-based

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[1] Pursuant to Supreme Court Rule 37.6, PhRMA hereby states that no counsel for a party has authored this brief in whole or in part, and that no person or entity, other than PhRMA or its members, has made a monetary contribution to the preparation or submission of this brief. Pursuant to Supreme Court Rule 37.3(a), the parties have consented to the filing of this brief. Their letters of consent have been filed with the Clerk of the Court.

pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. PhRMA's member companies invest nearly $19 billion annually in discovering and developing new medicines. These companies are the source of nearly all new drugs that are discovered and marketed throughout the world.

The pharmaceutical industry is based on science, from the discovery of promising new chemical entities through their testing, development, and distribution. Science also must play a vital role in product liability cases alleging injury from these products. Unless unreliable and speculative opinions are excluded, juries in these complex cases can award damages that are not founded on reliable scientific knowledge. Such awards threaten the enterprise of pharmaceutical research and development, and thus the availability of important new medicines.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), establishes the framework governing admission of scientific evidence to prevent unsupported theories from being presented to juries in the guise of expert testimony. It is vital for district courts to examine proffered testimony thoroughly and carefully, and to exclude testimony that does not meet *Daubert*'s demanding standards.

PhRMA has a strong interest in ensuring that the standard of appellate review established for a trial court's admissibility determinations under *Daubert* does not deter courts from excluding proffered evidence that is scientifically flawed. Accordingly, PhRMA is filing this brief to provide the Court its perspective on the standard of appellate review in the context of *Daubert*'s proper application in the district court, and on the serious consequences for the availability of medicines of unfounded product liability judgments.

SUMMARY OF ARGUMENT

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), requires trial courts to act as gatekeepers and to exclude from evidence proffered expert scientific testimony that lacks a sound scientific basis. In particular, *Daubert*, unlike the common law *Frye* test which the Federal Rules of Evidence superseded, directs district courts to conduct an independent assessment of the reliability and relevance of purportedly scientific evidence rather than to inquire merely whether the expert's methods are generally accepted in the scientific community. To carry out this charge in a meaningful manner, district courts must scrutinize each step in an expert's reasoning to ensure that the expert's opinions rest on a scientifically valid and pertinent foundation. The district court in the instant case performed an appropriately careful and searching review.

Such a rigorous application of *Daubert*'s framework is particularly important to safeguarding the development and availability of medicines. Pharmaceutical manufacturers face product liability claims that typically turn on scientific evidence regarding questions of causation that trigger *Daubert* and Federal Rule of Evidence 702. If courts permit unsupported pseudoscientific theories of causation to be presented to a jury, pharmaceutical firms could face baseless liability awards that would adversely affect the research and development of new medicines and the continued availability of existing ones. Accordingly, courts should be especially vigilant to exclude testimony that does not meet the *Daubert* standards and to grant summary judgment before trial where plaintiffs do not come forward with valid expert opinions to support their allegations.

The district courts should not be secondguessed by appellate courts when they carry out the complex inquiry

required by *Daubert*. Therefore, the courts of appeals should apply an abuse of discretion standard in reviewing decisions on the admissibility of scientific evidence. Less deferential review would only discourage district courts from performing their gatekeeper function under *Daubert*. In particular, the courts of appeals should not apply heightened scrutiny only to the exclusion of evidence, for such a one-way ratchet would provide a detrimental incentive to district courts to allow unsupported and scientifically flawed testimony to go to the jury.

ARGUMENT

I. *DAUBERT* REQUIRES THAT DISTRICT COURTS ACT AS GATEKEEPERS TO PREVENT PSEUDOSCIENTIFIC OPINIONS FROM REACHING THE JURY.

Daubert held that the Federal Rules of Evidence require trial judges to perform a "gatekeeping role" and screen purportedly scientific evidence to ensure that it is relevant and reliable. 509 U.S. at 589, 597. When a party proffers expert scientific evidence, the trial judge, in addition to qualifying a witness as an expert, must make a threshold determination "of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. Courts must not permit claimed scientific opinions that amount to no more than unsupported assertions or speculation to reach the jury. *See Claar v. Burlington N. R.R.*, 29 F.3d 499, 502 (9th Cir. 1994); *see also Gruca v. Alpha Therapeutic Corp.*, 51 F.3d 638, 643 (7th Cir. 1995) (criticizing district court for abdicating its gatekeeping

responsibilities).[2/]

Although district courts screened proffered scientific evidence prior to *Daubert*, *Daubert* interpreted the Federal Rules of Evidence to alter a court's gatekeeping role in certain important respects. First, *Daubert* held that the Federal Rules of Evidence, and Rule 702 in particular, supersede the common law *Frye* test, which most courts followed before *Daubert*, and require district courts to conduct their own independent assessment of scientific evidence rather than to inquire merely whether the expert's methods are generally accepted in the scientific community. *Daubert*, 509 U.S. at 587, 589, 597; *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923); Eric D. Green & Charles R. Nesson, *Problems, Cases, and Materials on Evidence* 649 (1983). Second, *Daubert*, again based primarily on Federal Rule of Evidence 702, outlined an analytical framework for courts to follow in making threshold admissibility determinations. 509 U.S. at 589-95. As discussed further below, to apply this framework properly and take its reinvigorated gatekeeping responsibility seriously, a court must carefully assess each link in an expert's chain of reasoning to ensure that the expert's opinions are based on a valid scientific methodology and are applicable to the facts and issues of a particular case.

2/ As the Supreme Court explained in *Daubert*, significant differences exist between scientific inquiry and legal inquiry. Although consideration of wide-ranging hypotheses are part of science's search for truth, "[c]onjectures that are probably wrong are of little use . . . in the project of reaching a quick, final, and binding legal judgment — often of great consequence — about a particular set of events in the past." *Daubert*, 509 U.S. at 597.

A. Under *Daubert*, District Courts Must Independently Assess the Reliability and Relevance of Proffered Expert Scientific Testimony.

Daubert charges district courts with taking an active role in reviewing scientific evidence, in contrast to the deferential role of *Frye*. As the Seventh Circuit has explained, the elimination of the *Frye* standard "shifted to the trial judge the responsibility for keeping 'junk science' out of the courtroom. It is a responsibility to be taken seriously." *Wilson v. City of Chicago*, 6 F.3d 1233, 1238-39 (7th Cir. 1993) (internal citation omitted), *modified on other grounds*, 1993 U.S. App. LEXIS 31,896 (7th Cir. Dec. 8, 1993), *cert. denied*, 511 U.S. 1088 (1994); *see also In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d 1124, 1132 (2d Cir. 1995) ("The *Daubert* Court significantly changed the standards governing the admissibility of scientific evidence by expanding district courts' discretion to evaluate the reliability and relevance of contested evidence."), *cert. denied*, 115 S. Ct. 1253 (1995); *Daubert v. Merrell Dow Pharmaceuticals*, 43 F.3d 1311, 1315 (9th Cir.) ("Federal judges ruling on the admissibility of expert scientific testimony face a far more complex and daunting task in a post-*Daubert* world than before."), *cert. denied*, 116 S. Ct. 189 (1995) [hereinafter *Daubert II*]. No matter how credentialed the expert, the court must ensure that the expert's opinions are grounded in a sound and pertinent scientific foundation. *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318-19 (7th Cir.), *cert. denied*, 117 S. Ct. 73 (1996).

This responsibility derives from the plain language of Federal Rule of Evidence 702, which requires, in relevant part, that expert opinion testimony (1) consist of "scientific knowledge" and (2) "assist the trier of fact to understand the

evidence or to determine a fact in issue."[3] *Daubert*, 509 U.S. at 589-92. To qualify as "scientific knowledge" and satisfy the first prong of this two-pronged test, testimony must be "derived by the scientific method" and have a "grounding in the methods and procedures of science." *Id.* at 590. Only opinions so validated are sufficiently reliable to be admitted into evidence. To "assist the trier of fact" and satisfy the second prong of Rule 702, an expert's opinion must have "a valid scientific connection to the pertinent inquiry." *Id.* at 592. That is, an expert's opinion must not only be grounded in science and hence generally reliable, it must be based on reasoning or methodology that applies to the disputed issue in a particular case. Reasoning or methodology that does not "fit" the case at hand is not relevant and, thus, not admissible. *Id.* at 591 (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985)).[4]

Daubert identifies four factors to guide a court's assessment of the scientific reliability and applicability of the theory or technique upon which the proffered scientific

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[3] In its entirety Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

[4] For example, as the Supreme Court explained in *Daubert*, expert testimony on the phases of the moon might be relevant to determining whether it was dark out on a given night, but would not be relevant to determining whether someone acted irrationally that night, unless credible evidence could validate the relationship between the phases of the moon and a person's behavior. 509 U.S. at 591.

evidence rests: (1) whether it can be tested empirically; (2) whether it has been subjected to peer review and publication; (3) what its error rate is; and (4) whether it has a high degree of general acceptance in the relevant scientific community. 509 U.S. at 593-94.[5/] Each factor can shed some light on the scientific validity of an expert's theory, and no single factor is determinative. *Id.* at 594-95. For example, although a theory or technique need not be generally accepted by other experts, as *Frye* required, minimal acceptance within the scientific community provides grounds for the court to view a theory skeptically. *Id.* at 594.

Daubert expressly provides that other factors, in addition to the four it outlines, might be germane to a court's scrutiny of scientific evidence, *id.* at 593, and courts have identified further relevant considerations. For example, the Ninth Circuit has held that developing an opinion solely for the purposes of litigation can cast doubt on its reliability, *Daubert II*, 43 F.3d at 1317, and the Third Circuit has held that courts can consider the degree to which an expert is qualified in evaluating whether his or her opinions are scientifically reliable, *In re Paoli*, 35 F.3d at 742.

Together these factors provide courts the means to scrutinize purportedly scientific evidence. However, they must be applied with rigor to carry out *Daubert*'s gatekeeping mandate properly, for "something doesn't become 'scientific

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[5/] Some courts treat these factors as applying only to the reliability determination. *See, e.g., In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994). In *Daubert*, this Court described the factors as relating to the overarching inquiry of whether testimony is *both* scientifically valid and applicable to the facts in issue. 509 U.S. at 593. Logically, the factors can assist a court's inquiry into both whether there is a valid basis for the expert's opinions in general, and whether there is a valid basis to apply those opinions to the facts of a particular case.

knowledge' just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were 'derived by the scientific method' be deemed conclusive." *Daubert II*, 43 F.3d at 1315-16.

B. The Only Meaningful Way to Assess the Reliability and Relevance of Purported Expert Scientific Testimony is to Scrutinize Carefully Each Step in the Expert's Reasoning to Ensure that it is Scientifically Valid and Pertinent to the Case at Hand.

An expert's scientific opinion can only be sound if each step in the reasoning that led to the opinion is sound. As one court has explained, "an expert who supplies nothing but a bottom line supplies nothing of value to the judicial process." *Rosen*, 78 F.3d at 319 (quoting *Mid-State Fertilizer Co. v. Exchange Nat'l Bank*, 877 F.2d 1333, 1339 (7th Cir. 1989)). To assess the reliability and relevance of scientific expert testimony in any real way, a trial court must scrutinize each aspect of the methodology that an expert uses to reach a conclusion. *See In re Paoli*, 35 F.3d at 745 ("*[A]ny* step that renders the analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible.*") (emphasis in original); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1401 (D. Or. 1996) (the trial judge must "ensure that in each step, from initial premise to ultimate conclusion, the expert faithfully followed valid scientific methodology").

As a preliminary matter, the trial court must verify that an expert has an appropriate foundation upon which to draw a conclusion. Opinions consisting purely of untested hypotheses are inadequate to satisfy *Daubert*'s strictures. *See Wheat v. Pfizer, Inc.*, 31 F.3d 340, 343 (5th Cir. 1994) (expert's "hypothesis" that combination of medicines plaintiff took for her neck pain may have caused plaintiff's hepatitis

should be excluded where expert lacked empirical studies or any other basis for his opinion.); *Porter v. Whitehall Lab., Inc.*, 9 F.3d 607, 614 (7th Cir. 1993) (doctor's theory that ibuprofen caused plaintiff's renal condition properly excluded where doctor could not point to studies, records, data, or other scientific basis for her opinion). So too are opinions based solely on anecdotal evidence, *Bradley v. Brown*, 852 F. Supp. 690, 699 (N.D. Ind.) (notwithstanding the claim of plaintiffs' experts to have experience with over 20,000 cases of multiple chemical sensitivity disorder ("MCS"), the district court excluded the expert's opinion as to the cause of the plaintiffs' MCS because it "would necessarily rest on uncontrolled past observations" and was "a far cry from the tested hypotheses foreseen as the basis of 'scientific knowledge' . . . under Rule 702"), *aff'd*, 42 F.3d 434 (7th Cir. 1994),[9] and those based on potentially biased data, *In re Paoli*, 35 F.3d at 763 (upholding district court's exclusion of expert where expert relied on plaintiffs' answers to questionnaires and failed to examine plaintiffs or review their medical records).

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[9] *See also Bradley*, 42 F.3d at 438 (holding that experts' opinions as to cause could be excluded as "merely anecdotal"); *O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090, 1107 n.19 (7th Cir. 1994) (doctor's prior experience with five cases of radiation-induced cataracts not a proper basis for opinion); *Porter*, 9 F.3d at 614 n.6 (doctor's "experience and first-hand observations" held insufficient basis for opinion on causation where doctor had encountered only about five cases of relevant disorder, none of which was linked to the alleged cause claimed by plaintiff); *Wade-Greaux v. Whitehall Lab., Inc.*, 874 F. Supp. 1441, 1481 (D.V.I.) (rejecting reliance on "individual human case reports" because "such data represent anecdotal information of chance associations, do not purport to assess cause and effect and have no epidemiological significance"), *aff'd mem.*, 46 F.3d 1120 (3d Cir. 1994); *Casey v. Ohio Medical Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (expert's opinion could not be based on study that "was not an epidemiological study," but only "a compilation of case reports").

Similarly, courts have held that animal studies, without confirmation through rigorous epidemiological or other evidence in humans, do not provide a sufficient basis for an expert to assert causation in humans. For example, in *Raynor v. Merrell Pharmaceuticals Inc.*, the court of appeals held that the district court properly excluded an expert's opinion that Bendectin caused birth defects in part because the animal studies that the expert relied upon were contradicted by relevant epidemiological evidence. 104 F.3d 1371, 1375 (D.C. Cir. 1997). As the *Raynor* court explained, "[t]he only way to test whether data from non-human studies can be extrapolated to humans would be to conduct human experiments or use epidemiological data." *Id.*; *see also Daubert II*, 43 F.3d at 1320 (requiring experts to "point to some authority for extrapolating human causation" from animal studies); *Wade-Greaux*, 874 F. Supp. at 1480 ("[T]he theory of the plaintiff's expert witnesses that they can directly extrapolate from experimental animal studies without supportive positive human studies to opine on causation in humans is one that has an extraordinarily high rate of error.").

If a party can demonstrate that the foundation upon which its expert's conclusions rest is sufficiently reliable, the court must next examine whether the expert followed a scientifically valid reasoning process in drawing conclusions from that foundation. *Daubert* cautions that courts must focus on principles and methodology and not the substance of an expert's conclusions. 509 U.S. at 595. Nonetheless, even a limited inquiry into an expert's methodology must consider how the expert reached his or her conclusions from some established premise. As the dissenting judge in the decision below stated, "We should not require the trier of fact to accept blindly the expert's word to fill the analytical gap between proffered 'scientific knowledge' and the expert's conclusions. . . . [T]he trial court 'gatekeeper' has broad discretion to decide whether a leap of faith across the analytical gap is so

great that, without further credible grounds, the testimony is inadmissible." Pet. App. 18a (Smith, J., dissenting); *see also Hall*, 947 F. Supp. at 1411 ("[A]n evaluation of whether scientific methodology is valid for *Daubert* purposes should include an examination of how the proffered conclusions relate to the bases upon which the expert relies.").

For example, an expert cannot cite legitimate data as the basis of an opinion, but then selectively use such data to reach a conclusion. *See Daubert II*, 43 F.3d at 1320 (requirement that expert's methodology be based on "sound scientific principles" means that plaintiffs' epidemiologists would have to "validate their reanalyses by explaining why they chose only certain of the data that was available"); *In re Paoli*, 35 F.3d at 773 (reanalyzing data based on selection of limited samples "does not appear reliable"). Similarly, an expert's conclusion that some event caused a claimed effect is flawed where the expert fails to account for and rule out alternative causes. *See In re Paoli*, 35 F.3d at 768; *Claar*, 29 F.3d at 502; *Porter*, 9 F.3d at 616. Of course, an expert also cannot cite as the basis for a proposition some source that does not in fact support the expert's conclusions. For example, in *Conde v. Velsicol Chem. Corp.*, the court held that the plaintiffs' expert could not base his opinion that an insecticide caused long-term health effects on published critiques of negative epidemiological studies where the critiques merely called for further study and did not provide any affirmative support for the claimed causation. 24 F.3d 809, 814 (6th Cir. 1994).

Relatedly, under *Daubert*'s second prong (the "fit" test), courts must ensure that experts do not inappropriately apply otherwise reliable scientific evidence to contexts in which it is not relevant. In effect, when an expert overstates the relevance of scientific evidence in this manner, the expert renders his or her conclusions methodologically unsound and unreliable. For example, an expert's opinion that the

defendant's nicotine patch caused the plaintiff's heart attack amounted to no more than an "inspired [] hunch," even though he cited a potentially valid animal study that nicotine can cause arterial plaque in the long term, because the study could not explain how a nicotine overdose from the patch could have precipitated plaintiff's heart attack in the short term. *Rosen*, 78 F.3d at 319; *see also Hall*, 947 F. Supp. at 1411-12 (studies based on crystalline silica cannot support conclusions that breast implants caused disease given failure to establish that silicone gel in implants degrades to silica).

Courts must pay particular attention to relevance problems in cases turning on issues of causation. For example, evidence that exposure to a substance can cause harm in general does not provide a reliable basis for establishing that exposure caused a particular harm. *See, e.g., Casey*, 877 F. Supp. at 1385 (refusing to admit expert testimony that exposure to halothane could cause chronic active hepatitis because the study on which the expert based his opinion established only that halothane exposure might be harmful and might cause some liver disorders, not that such exposure could cause hepatitis). Similarly, evidence that exposure to a large dose of a substance can cause harm does not provide a reliable basis for establishing that harm can be caused by a lower dose. *See Porter*, 9 F.3d at 615 (excluding testimony that ibuprofen could aggravate an independently developed kidney problem where expert "admitted that this aggravation would be dose-related and would require a far greater dosage than [the deceased] ingested"); *Wade-Greaux*, 874 F. Supp. at 1454, 1457, 1464, 1480 (holding that the reliability of animal studies is undermined by the enormous dosages administered and characterizing as "untenable" expert's assumption that level of "dose is irrelevant to humans"); *Chikovsky v. Ortho Pharmaceutical Corp.*, 832 F. Supp. 341, 345-46 (S.D. Fla. 1993) (excluding doctor's testimony that Retin-A, a Vitamin A derivative, caused birth defects, where opinion was based

on studies linking "high doses" to fetal harm, but doctor admitted that he did "not know how much Retin-A [the plaintiff] might have absorbed through her skin during her pregnancy" and that he "did not know at what dosage level Vitamin A became unsafe for use by pregnant women"). More generally, an expert cannot stretch an opinion based on certain assumptions to a case where those assumptions have not been established. *See, e.g.*, *Pries v. Honda Motor Co.*, 31 F.3d 543, 545 (7th Cir. 1994) (excluding expert opinion that seatbelt latch had come open during accident, because although expert testified that latch could come open if it struck a hard surface, there was no evidence or opinion that similar forces occurred commonly in a crash).

Only by assessing each of these aspects of an expert's reasoning can a court ensure that the opinion is grounded in science. One weak link in an expert's methodological chain fatally flaws the conclusions that the methodology yields.

C. In the Instant Case, the District Court Properly Executed its Gatekeeping Function Under *Daubert*.

The contrast between the application of *Daubert* by the district court and by the court of appeals in this case is illustrative of the difference between a meaningful review of an expert's purportedly scientific methodology and a refusal to take seriously *Daubert*'s directive to admit only "scientific knowledge." Out of a misplaced concern for turning "judges into jurors or surrogate scientists," Pet. App. 7a, the court of appeals focused on whether the experts' opinions "as a whole" constituted mere speculation, Pet. App. 13a, rather than examining critically the foundation for and reasoning process used in reaching those opinions. The district court correctly questioned the animal studies that the plaintiffs' experts relied upon because there were only two studies, they involved massive doses of PCBs, and they were preliminary. Pet. App.

61a. The court of appeals, though, criticized the district court for focusing on "individual pieces of evidence," which should be viewed "in their entirety" as "building blocks of a perfectly reasonable conclusion." Pet. App. 12a. Yet, even if the court of appeals is correct that the ultimate inquiry is the reliability of an expert's final opinions, it is impossible for a court to make that ultimate determination without carefully examining the particulars upon which an opinion is based.

Notably, the court of appeals failed to offer an explanation for rejecting the district court's finding that the epidemiological studies were flawed because they were "either equivocal or not helpful to Plaintiffs," Pet. App. 63a, or that the animal studies could not support the plaintiffs' claims because they were performed with excessively high doses, Pet. App. 61a. Rather, the court of appeals simply noted that the experts "utilized numerous scientific studies and authorities," Pet. App. 10a, and it relied on the experts' own representations that they employed generally accepted and long-established methods and procedures to reach their conclusions, Pet. App. 10a-11a. As the concurrence makes explicit, the court of appeals refused to evaluate "[w]hether the conclusions advanced from the stated premises in fact follow . . . ." Pet. App. 16a (Birch, J., concurring). Presumably, then, under the approach of the court of appeals, an expert has free rein to offer opinions so long as he or she asserts that they flow from sources that the court has found valid. Such an approach would gut *Daubert* and Rule 702, and would allow an expert's unsupported contentions to masquerade as scientific opinion. In contrast, the district court's careful approach, examining particular claims and pieces of evidence to make an overall assessment of an expert opinion's reliability, correctly preserves the court's gatekeeping role.

II. THE PROPER APPLICATION OF *DAUBERT* BY DISTRICT COURTS IS PARTICULARLY IMPORTANT TO THE CONTINUED DEVELOPMENT AND AVAILABILITY OF MEDICINES.

The product liability claims that are brought against pharmaceutical companies typically turn on scientific evidence, and, in particular, on scientific evidence of causation, like the claim against the pharmaceutical manufacturer in *Daubert* itself. As such, they come directly within *Daubert*'s purview and give the pharmaceutical industry a substantial interest in the proper application of *Daubert* and Rule 702. To put the Court's decision in this case in context, we provide here a brief discussion of the significance of *Daubert* in pharmaceutical product liability cases. The importance of properly applying *Daubert* in these cases is heightened because the potential for unreliable theories to create meritless liabilities is particularly acute in the pharmaceutical field. As Marcia Angell, M.D., the Executive Editor of the New England Journal of Medicine, explains, "[t]o evaluate whether a product has caused a disease is difficult for nearly anyone. For a jury it is especially difficult, because its members usually have no competence in the area. They are often left to make judgments largely on the basis of the emotional appeals of the lawyers and their expert witnesses."[1/]

[1/] Marcia Angell, *Science on Trial* 204 (1996). Angell further explains that the tort system encourages lawyers under contingency fee arrangements to bring meritless suits, impose burdensome defense costs on defendants, and collect quick settlements. *Id.* at 203. As a result:

> scientific testimony in the courtroom is often at most only marginally related to scientific evidence. To be sure, there are
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> (continued...)

The imposition of unfounded liabilities on pharmaceutical researchers and manufacturers creates serious social costs by adding to the substantial liabilities that pharmaceutical firms already face,[3/] deterring research and innovation, and forcing companies to take safe and effective products off the market.[2/] As one commentator has explained, while "[t]he

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[1/](...continued)

> superficial matters of form that may suggest a resemblance between science in and out of the courtroom. Expert witnesses may wear white coats, be called 'doctor,' purport to do research, and talk scientific jargon. But too often they are merely adding a veneer to a foregone, self-interested conclusion. Sometimes they spin theories that they say are supported by their expertise or experience. Or they may refer vaguely to research. Very often, however, the 'research' is their own and it is unpublished and unavailable. The point is that they are not required to produce their evidence, and they usually do not. The result is a growing gap between scientific reality and what passes for it in the courtroom.

Id. at 132. According to Angell, "[t]he *Daubert* decision was a brave step toward remedying the situation." *Id.*

[3/] *See* W. Kip Viscusi, Michael J. Moore, & James Albright, *The Effect of Products Liability Litigation on Innovation: A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 Seton Hall L. Rev. 1418, 1434 (1994) ("The pharmaceutical industry, which is one of the most innovative industries in the economy, has been particularly hard hit by the surge in liability costs.").

[2/] *See* Steven Garber, The Institute for Civil Justice, *Product Liability and the Economics of Pharmaceuticals and Medical Devices* 142 (1993) ("Effects on innovative effort may be the most important element of the effects of liability on the economic performance of these industries."); Richard J. Mahoney & Stephen E. Littlejohn, *Innovation on Trial: Punitive Damages Versus New Products*, 246 Science 1395, 1397 (Dec. 15, 1989) ("The result of this liability expansion has been a slowing of innovation in entire fields of inquiry, especially in those having to do with health care.").

economics of the industry impel companies to innovate, . . . liability concerns may steer them away from some types of innovation that appear to pose relatively large liability threats."[10/] Unfortunately, the product areas with the largest potential liability are often those with the greatest potential public health benefits. For example, as early as 1988, the American Medical Association noted that rising liability insurance costs were hindering the testing of new drugs and devices related to pregnancy and contraception.[11/] An FDA expert advisory panel,[12/] the American Academy of

[10/] Garber, *supra* note 9, at 144. The American Medical Association has similarly found that:

> Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy, but because product liability suits have exposed manufacturers to unacceptable financial risks.

American Medical Association, *Report of the Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies* 1 (1988) [hereinafter *AMA Report*].

[11/] *AMA Report*, *supra* note 10, at 9; *see also* Peter W. Huber, *Liability: The Legal Revolution and Its Consequences* 155 (1988).

[12/] FDA Advisory Panel on Review of Bacterial Vaccines and Toxoids, *Biological Products: Bacterial Vaccines and Toxoids; Implementation of Efficacy Review*, *reprinted in* 50 Fed. Reg. 51002, 51006 (Dec. 13, 1985) ("attempts to improve vaccines further will be hampered" by tort liability).

Pediatrics,[13/] the Institute of Medicine,[14/] and commentators[15/] all agree that liability concerns have impeded pharmaceutical research and development.

Even when drug companies successfully defend against a suit, they (and society) can face substantial costs.[16/] The case of Bendectin, which was at issue in *Daubert* itself, provides a cautionary example.[17/] Bendectin was the only prescription drug ever approved in the United States to treat nausea and vomiting in pregnancy. Introduced in 1956, the drug was used by more than 30 million pregnant women. Beginning in 1969, assertions that Bendectin could produce congenital birth defects began to appear in the scientific literature. Although no scientific study ever proved a causal relationship between Bendectin and birth defects, and the Food and Drug Administration repeatedly affirmed the drug's

[13/] *Vaccine Injury Compensation: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong. 115 (1986) (statement of Dr. Martin H. Smith, President, American Academy of Pediatrics) ("research efforts for new and improved vaccines have been chilled" because of liability concerns).

[14/] Institute of Medicine, *Vaccine Supply and Innovation* 11 (1985) ("apprehensions [concerning liability] are a disincentive to investment in the development of new (or improved) immunizing agents"); *id.* at 2 (resolution of liability issues necessary so that "the potential of new technologies [may] be fully realized").

[15/] *E.g.*, Huber, *supra* note 11, at ch. 10.

[16/] Marvin E. Jaffe, *Regulation, Litigation, and Innovation in the Pharmaceutical Industry: An Equation for Safety*, *in* National Academy of Engineering, *Product Liability and Innovation: Managing Risk in an Uncertain Environment* 120, 126 (Janet R. Hunziker & Trevor O. Jones eds.) (1994).

[17/] *See id.*

safety, nearly 1,700 suits were brought against the manufacturer. The manufacturer won nearly every case. Yet despite the overwhelming absence of scientific evidence that its product caused birth defects, the manufacturer had to withdraw Bendectin from the marketplace in 1983, because its annual legal costs were almost as great as its annual sales revenue. Given the fate of Bendectin, "it is unlikely that any new drug will be developed to close the therapeutic gap,"[18] to the detriment of millions of women.

Thus, it is especially important that courts vigilantly exclude testimony that does not meet *Daubert*'s standards. In so doing, courts can minimize the costs of baseless litigation by granting summary judgment where litigants lack valid expert opinions to support their allegations. *See Lust v. Merrell Dow Pharmaceuticals*, 89 F.3d 594, 598 (9th Cir. 1996); *Claar*, 29 F.3d at 500; *O'Conner*, 13 F.3d at 1107; *Porter*, 9 F.3d at 612, 616-17. Even if courts admit scientific evidence, they can apply the factors that *Daubert* outlines to determine whether such evidence, even if admissible, is sufficient to withstand a summary judgment or directed verdict motion. *See Conde*, 24 F.3d at 813-14; *Elkins v. Richardson-Merrell, Inc.*, 8 F.3d 1068, 1073 (6th Cir. 1993), *cert. denied*, 510 U.S. 1193 (1994). As *Daubert* explained, these "safeguards" provide further protections against "a 'free-for-all' in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions." 509 U.S. at 595; *see also Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360-61 (6th Cir.) (pre-*Daubert* case cited with approval by *Daubert* holding that plaintiff's scientific evidence was admissible but insufficient to withstand defendant's motion for summary judgment), *cert. denied*, 506 U.S. 826 (1992); *Wade-Greaux*, 874 F. Supp. at 1485 (same).

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[18] *Id.*

III. TO ENSURE THE PROPER APPLICATION OF *DAUBERT*, TRIAL COURT RULINGS ON THE ADMISSIBILITY OF EXPERT SCIENTIFIC OPINIONS SHOULD ONLY BE REVIEWABLE ON APPEAL FOR AN ABUSE OF DISCRETION.

In light of the complex inquiry that district courts must conduct under Rule 702, their decisions on the admissibility of expert testimony should receive considerable deference and be reviewed on appeal only for an abuse of discretion. Indeed, ten courts of appeals have adopted either an abuse of discretion or manifestly erroneous standard of appellate review and accorded district courts wide discretion in applying *Daubert*. *See* cases cited at Pet. App. 6-10.

Applying a de novo standard of appellate review would encourage appellate courts to secondguess district courts and would discourage district courts from excluding improper expert testimony. Whatever consistency de novo review might produce would come at the expense of the meaningful application of *Daubert* and Rule 702 and the expeditious dismissal of baseless liability suits. At the very least, the Court should reject the heightened scrutiny employed by the court of appeals here only for the exclusion of expert testimony, *see* Pet. App. 4a; *see also In re Paoli*, 35 F.3d at 750. Adopting such a one-way ratchet would create a dangerous incentive for district courts to allow unsupported and scientifically flawed testimony to go to the jury.

CONCLUSION

The judgment of the court of appeals should be reversed.

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
and MONSANTO COMPANY,
Petitioners,

v.

ROBERT K. JOINER and KAREN P. JOINER,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

---

BRIEF OF CHEMICAL MANUFACTURERS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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IN THE

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GENERAL ELECTRIC COMPANY,
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**On Writ of Certiorari to the
United States Court of Appeals
for the Eleventh Circuit**

BRIEF OF CHEMICAL MANUFACTURERS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

Amicus curiae respectfully prays that this Court reverse the Eleventh Circuit's ruling in this case and reinstate the District Court's judgment in favor of the Petitioners. *Amicus* has obtained consent from all parties to file this brief. Correspondence evidencing consent has been provided to the Clerk of this Court.

INTEREST OF *AMICUS CURIAE* *

The Chemical Manufacturers Association ("CMA") is a non-profit trade organization whose member companies produce, market, and use industrial chemicals. Its members comprise more than 90 percent of the productive capacity for basic industrial chemicals in the United States. The chemical industry employs over a million workers in this country, and produces about 1.8 percent of the U.S. gross domestic product. On a value-added basis, the industry is about 10.3 percent of U.S. manufacturing. Petitioner Monsanto Company is a CMA member, as is General Electric Plastics, a business wholly-owned by Petitioner General Electric Company.

CMA is concerned about this case because the Eleventh Circuit's decision undermines this Court's ruling in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *Daubert* requires that federal trial judges act as gatekeepers to determine "whether the reasoning or methodology underlying [an expert's] testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. The Eleventh Circuit, however, has announced that when expert testimony is excluded under *Daubert*, the ruling is subject to "particularly stringent" review. On the other hand, if a court *admits* such testimony its ruling would be subject to no special scrutiny.

This outcome-dependent one-way strict scrutiny standard of review discourages trial courts from exercising the control over experts that *Daubert* requires, and it thrusts on appellate courts the kind of detailed factfinding for which trial courts are much better suited. Indeed, in this case the Eleventh Circuit did not address the experts'

* No counsel for any party authored any part of this brief, and no person other than *amicus curiae*, its members, or its counsel made any monetary contribution to the preparation or submission of the brief.

reasoning and methodology, but focused instead on their qualifications and the sources of information on which they relied.

The inquiry into scientific validity that *Daubert* requires has led to better informed rulings on the admissibility of expert evidence, and ultimately to better informed verdicts, but the Eleventh Circuit's decision (and a similar decision from the Third Circuit) threaten its continued effectiveness. For CMA and its constituent members, who face putatively scientific testimony from a wide variety of experts, discouraging judicial gatekeeping in this area raises grave concerns. When experts are allowed to give opinions in court that are not the result of scientifically valid reasoning and methodology, defendants sometimes pay for injuries or damages they did not cause or that may not even exist. The American consumer also pays; prices go up and some products are never developed or never brought to market. *Daubert* has reduced the use of invalid and unreliable expert testimony, and this case should not be allowed to vitiate its salutary effect.

STATEMENT OF THE CASE

The Plaintiffs (here Respondents) in this case are a husband and wife who claimed the husband's lung cancer was caused by his alleged exposure to PCBs (polychlorinated biphenyls). They also claimed he was exposed to furans and dioxins. All of these exposures allegedly resulted from the husband's work with transformers at the municipal utility where he was employed as an electrician. The District Court found the Plaintiffs' expert testimony on causation inadmissible under Rule 702 of the Federal Rules of Evidence, as interpreted by this Court in *Daubert*, and granted the Defendants' motion for summary judgment. *Joiner v. General Electric Co.*, 864 F.Supp. 1310 (N.D. Ga. 1994).

In particular, the trial court found there was insufficient evidence of exposure to furans and dioxins, and that the

expert testimony did not establish a scientifically valid link between PCBs and lung cancer. The experts had relied on animal studies, and while the court did not hold that testimony based on such studies was invariably inadmissible, in this case the reasoning connecting the studies to the conclusion that PCBs cause lung cancer in humans was fatally flawed. There were only two studies; both had involved massive doses; and one of the Plaintiffs' own experts had conceded their preliminary nature. *Id.* at 1323. Overall, the "analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of [causation was] too wide." *Id.* at 1326 (quoting *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir.), *cert. denied*, 113 S.Ct. 84 (1992) (involving similar isues in the context of litigation concerning the anti-nausea drug Bendectin)).

Nothwithstanding the District Court's careful and detailed analysis of the experts' reasoning and methodology, the Eleventh Circuit reversed, holding in a 2-1 decision that a trial judge's exclusion—*but not admission*—of expert testimony warrants "particularly stringent" review. *Joiner v. General Electric Co.*, 78 F.3d 524, 529 (11th Cir. 1996). The two judge majority then undertook its own reinterpretation of the Plaintiffs' evidence. The majority described the studies relied upon by the experts, but never discussed how the expert opinions were derived from those studies. This omission prompted the dissenting judge to observe that experts cannot simply cite studies "and then, with blue smoke and sleight of hand, leap to [conclusions.]" *Id.* at 537 (Smith, J., dissenting).

SUMMARY OF ARGUMENT

Because of its explicitly acknowledged bias against exclusion of questionable expert testimony, the Eleventh Circuit's one-way strict scrutiny standard of review is at odds with this Court's mandate in *Daubert* that district judges must act as gatekeepers to ensure the reliability and relevance of expert scientific evidence. The one-way strict scrutiny approach, which has been adopted by only the Third and Eleventh Circuits, discourages trial judges from fulfilling this mandate. It also is contrary to the deference traditionally accorded trial court rulings about the admissibility of expert testimony. This deferential approach, which reflects recognition that such decisions require detailed case-by-case analysis, has not been altered by the adoption of the Federal Rules of Evidence. Although the rules have eliminated arcane procedural barriers to admissibility, they have not changed the requirement that expert testimony be reliable and trustworthy.

The Third Circuit, which the Appellate Court in this case cited in support of one-way strict scrutiny, *Joiner*, 78 F.3d at 529, has made clear that part of the rationale for such an approach is concern that if "district judges set the [admissibility] threshold too high . . . [it] will in fact force plaintiffs to prove their case twice." *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 750 (3d Cir. 1994), *cert. denied*, 115 S. Ct. 1253 (1995). The standard for reviewing the correctness of a trial court's ruling on the admissibility of expert testimony should not, however, depend on which party is most affected by the inquiry into reliability and relevance. Nor should it depend on how such a ruling might affect the ultimate outcome of a case. No matter which party is impacted, expert testimony should be excluded when an expert uses scientifically invalid reasoning and methodology.

The hazards of excessive review by an appellate court are nowhere more apparent than in this case. *Daubert* requires an assessment of an expert's reasoning and methodology, but unlike the trial court, the Eleventh Circuit looked only at the qualifications of the two experts whose testimony was at issue, and at the information upon which they had relied. The analytical gap between that information and the experts' conclusions was unaddressed, largely because the panel majority misunderstood and misapplied

this Court's admonition in *Daubert* to focus on principles and methodology rather than conclusions. A scientific conclusion is the culmination of scientific reasoning, not something completely divorced from the methodology that led to it.

The Eleventh Circuit applied the wrong standard of review in this case, and its analysis of the Plaintiffs' expert testimony under *Daubert* ignored the absence of reasoned explanations for the experts' conclusions. The decision below should be reversed and the District Court's judgment for the Defendants reinstated.

ARGUMENT

I. THE ELEVENTH CIRCUIT'S ONE-WAY STRICT SCRUTINY STANDARD OF REVIEW IS AT ODDS WITH BOTH *DAUBERT* AND THE PRINCIPLES OF APPELLATE REVIEW.

The one-way strict scrutiny standard adopted by the Eleventh Circuit is explicitly biased against district court decisions to exclude expert testimony, and thus directly at odds with this Court's mandate in *Daubert* that trial judges must assess the reliability and relevance of such evidence as a preliminary matter. The only precedent for discouraging the application of *Daubert* is the Third Circuit's decision in *Paoli*, which except for this case has not been followed by other courts. Even the Third Circuit has not always applied its own holding.

Beyond conflicting with *Daubert*, the one-way strict scrutiny approach reflects fundamental misunderstandings about appellate review of admissibility decisions. Appellate courts traditionally have accorded trial judges broad discretion in this area, especially for expert testimony, which requires detailed case-by-case analysis. The Federal Rules of Evidence have not changed this approach. Under Rule 104(a), trial judges have authority to determine

admissibility as a preliminary matter, and there is nothing in Rule 702 or elsewhere in the rules that would limit this authority based on the result-oriented preference for admissibility that the Third and Eleventh Circuits would impose. The "liberal thrust" of the rules removes arcane procedural impediments to the introduction of expert testimony, such as the former requirements regarding hypothetical questions, but the rules have not lowered the threshold of reliability and trustworthiness.

Varying the scope and intensity of appellate review based on the outcome below rather than the degree of authority and responsibility assigned to the trial judge upsets the allocation of roles between appellate and trial courts. Distinctly different roles have developed because the institutional strengths and advantages of trial courts are not the same as the strengths and advantages of appellate courts. Even if a statute or policy favors a party or an outcome, which is not the case in tort litigation, such a preference would not affect the rules of evidence. Nor would it affect the role of a trial court in determining if evidence is admissible.

A. One-Way Strict Scrutiny Is Contrary to *Daubert*.

When a witness testifies as an expert about science, his or her testimony must in fact constitute valid scientific knowledge that is relevant to the case at hand. This requirement flows naturally and directly from the plain language of Federal Rule of Evidence 702, which allows opinion testimony from a qualified expert if "scientific . . . knowledge will assist the trier of fact." As *Daubert* makes clear, '[t]he adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' denotes more than subjective belief or unsupported speculation." [1] Requiring "that an expert's

[1] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993).

testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." [2]

Daubert further requires, in accordance with Rule 104(a) of the Federal Rules of Evidence, that trial judges must determine "at the outset" whether "the reasoning or methodology underlying [an expert's] testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." [3] Thus, trial courts are clearly obligated to exclude expert testimony when the expert's reasoning or methodology is invalid. Such exclusion may "on occasion [prevent] the jury from learning of authentic insights and innovations. [But that] . . . is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes." [4]

In the almost four years since this Court's decision in *Daubert*, most District Courts have heeded its message.[5]

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[2] *Id.*

[3] *Id.* at 592-93.

[4] *Id.* at 597.

[5] *See, e.g., Cuevas v. E.I. duPont de Nemours & Co.*, 956 F.Supp. 1306, 1312 (S.D. Miss. 1997) (excluding testimony of toxicologist and noting that toxicology "requires a determination of what dose-response relationship exists between the element in question and the harm that has possibly been caused"); *Cartwright v. Home Depot U.S.A., Inc.*, 936 F.Supp. 900, 903-4 (M.D. Fla. 1996) (excluding testimony of toxicologist regarding alleged link between latex paint and asthma where expert knew neither the plaintiffs' exposure level, nor the level required to cause asthma); *Haggerty v. Upjohn Co.*, 950 F.Supp. 1160, 1163 (S.D. Fla. 1996) (excluding medical causation testimony where expert's methodology consisted of reviewing various sources of information, such as case reports and references in textbooks); *In re TMI Litig. Consolidated Proceedings*, 927 F.Supp. 834, 858-66 (M.D. Pa. 1996) (summary judgment granted after extensive *Daubert* hearings resulted in exclusion of most of plaintiffs' expert testimony); *Cavallo v. Star Enterprise*, 892 F.Supp. 756, 763 (E.D. Va. 1995) (excluding testimony

Furthermore, most Circuit Courts have deferred to trial judges who have conducted the kind of inquiry into scientific validity that *Daubert* requires. Most appellate courts have applied an "abuse of discretion," [6] "clear error," [7] or "manifestly erroneous" [8] standard of review. Only the Third and Eleventh Circuits have bucked this trend by discouraging exclusion, and even the Third Circuit has not uniformly followed *Paoli*.[9] If the Eleventh Circuit's decision in this case is allowed to stand, however, much of the progress wrought by *Daubert* will be placed in serious jeopardy.

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of toxicologist who had not used proper methodology), *aff'd in relevant part*, 100 F.3d 1150 (4th Cir. 1996), Petition for Cert. filed March 19, 1997, No. 96-1493; *Whiting v. Boston Edison Co.*, 891 F.Supp. 12, 18 (D. Mass. 1995) (excluding epidemiological testimony because expert's methodology was "replete with factual and mathematical errors"); *Schmaltz v. Norfolk & Western Railway Co.*, 878 F.Supp. 1119, 1121-22 (N.D. Ill. 1995) (excluding testimony regarding alleged link between pesticide exposure and reactive airway dysfunction syndrome where theory of causation had not been subject to peer review); *Wade-Greaux v. Whitehall Laboratories, Inc.*, 874 F.Supp. 1441, 1477 (D. V.I. 1994) (excluding testimony regarding alleged causal link between over-the-counter cold remedy and birth defects because experts' efforts to extrapolate directly from animal studies was not a valid scientific methodology), *aff'd*, 46 F.3d 1120 (3d Cir. 1994).

[6] *See, e.g., Cavallo v. Star Enterprise*, 100 F.3d 1150, 1154 (4th Cir. 1996) Petition for Cert. filed March 19, 1997, No. 96-1493; *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 320 (7th Cir. 1996); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995).

[7] *See, e.g., Borawick v. Shay*, 68 F.3d 597, 601 (2d Cir. 1995).

[8] *See, e.g., United States v. Sepulveda*, 15 F.3d 1161, 1183 (1st Cir. 1993); *Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 196 (5th Cir. 1996).

[9] In *Habecker v. Clark Equipment Co.*, 36 F.3d 278, 289 (8th Cir. 1994), decided less than three weeks after *Paoli*, another panel of the circuit applied "a clear abuse of discretion" standard to affirm the trial court's exclusion of the plaintiff's expert testimony.

B. One-Way Strict Scrutiny Is Contrary to the Traditional Deference Accorded Trial Court Evidentiary Rulings.

The requirement that trial judges assess the scientific validity of an expert's reasoning and methodology reflects this Court's confidence in their capability to conduct such a review.[10] It also reflects the well-established pre-*Daubert* rule that a trial court's decision to admit or exclude expert evidence should be accorded great deference.[11] As this Court held in *Salem v. United States Lines Co.*,[12] such a decision is to be sustained unless it is "manifestly erroneous." [13] The *Salem* opinion cited with approval to *Congress and Empire Spring Co. v. Edgar*,[14] which held that

> Cases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous.[15]

Pre-*Daubert* courts took this deferential approach for sound policy reasons that *Daubert* clearly reinforces. As

[10] *Daubert*, 509 U.S. at 593. *See also Michelson v. United States*, 335 U.S. 469, 488 (1948) (Frankfurter, J., concurring) ("If the United States District Courts are not manned by judges of such qualities, appellate review, no matter how stringent, can do very little to make up for the lack of them.")

[11] *Se, e.g., Brown v. Parker-Hannifin Corp.*, 919 F.2d 308, 311 (5th Cir. 1990) (decision to exclude expert testimony reversed only for manifest error); *Logan v. Dayton Hudson Corp.*, 865 F.2d 789, 790 (6th Cir. 1988) (abuse of discretion standard, which was "defined as a definite and firm conviction that the trial court committed a clear error of judgment"); *Universal Athletic Sales Co. v. American Gym, Recreational & Athletic Equip. Corp., Inc.*, 546 F.2d 530, 537 (3d Cir. 1976) (trial court decisions regarding competency of expert witnesses reviewed for abuse of discretion).

[12] 370 U.S. 31 (1962).

[13] *Id.* at 35.

[14] 99 U.S. (9 Otto) 645 (1879).

[15] *Id.* at 658.

Judge Weinstein and Professor Berger state in their treatise, decisions about the admissibility of expert testimony require detailed, case-by-case analysis, and trial judges therefore must be accorded broad discretion in deciding to admit or exclude such testimony.[16] *Daubert*, which specifically mandates more detailed trial court review of disputed expert evidence than in the past, can hardly be understood as having reduced the discretion accorded trial judges.[17]

C. There Is No Justification for One-Way Strict Scrutiny in the Federal Rules of Evidence.

An important part of the Eleventh Circuit's rationale for its one-way strict scrutiny standard of review was its understanding that "the Federal Rules of Evidence governing expert testimony display a preference for admissibility." [18] In fact, the rules do not incorporate such a preference. Though they were intended to "[relax] the traditional barriers to 'opinion' testimony," [19] removing arcane and anti-

[16] 3 J. Weinstein & M. Berger, WEINSTEIN'S EVIDENCE ¶ 702(2) at 22-23 (1993).

[17] Even the Third and Eleventh Circuits routinely applied an abuse of discretion standard to the exclusion of unscientific opinion testimony well after the adoption of Rule 702. *United States v. Grizzle*, 933 F.2d 943, 949 (11th Cir. 1991); *United States v. Cross*, 928 F.2d 1030, 1049 (11th Cir. 1991) ("A trial court has wide discretion in determining whether to exclude expert testimony, and its action will be sustained on appeal unless manifestly erroneous."); *Gentry v. RTC*, 937 F.2d 899, 916 (3d Cir. 1991); *United States v. Stevens*, 935 F.2d 1380, 1397 (3d Cir. 1991) (Becker, J.). It was not until this Court's decision in *Daubert* that these two circuits discovered a preference for admission in Rule 702, and that this preference requires a special one-way strict scrutiny standard of review. It would appear that what is afoot is more a response to *Daubert* than to the Federal Rules of Evidence.

[18] *Joiner v. General Electric Co.*, 78 F.3d 524, 529 (11th Cir. 1996).

[19] *Daubert*, 509 U.S. at 588 (quoting *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988)).

quated impediments to the use of expert witnesses is not the same thing as creating a bias in favor of admitting their testimony. The rules do not relax the requirements of reliability and relevance.

The Advisory Committee Notes to Rule 702 make clear that this rule was intended to allow experts to explain and clarify evidence even if their testimony was not in the form of an opinion.

> Since much of the criticism of expert testimony has centered upon the hypothetical question, it seems wise to recognize that opinions are not indispensable and to encourage the use of expert testimony in non-opinion form when counsel believes the trier can itself draw the requisite inference.

The rule was also intended to broaden the definition of expert to include anyone with specialized knowledge, whether obtained through education, training, or experience. The notes are absolutely silent, however, regarding any preference for admissibility or any willingness to accept less than reliable evidence.

This Court's decision in the *Beech Aircraft* case further discussed the rules' relaxation of traditional barriers. Again, there is no hint of any preference for admissibility. Instead, the decision observes that "Rules 702-705 permit experts to testify in the form of an opinion, and without any exclusion of opinions on 'ultimate issues.' "[20] Thus, the liberalization effected by the adoption of the Rules provides no justification for a one-way strict scrutiny standard of appellate review that discourages trial judges from evaluating expert testimony critically.

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[20] *Beech Aircraft*, 488 U.S. at 169.

D. One-Way Strict Scrutiny Upsets the Rational Allocation of Responsibility Between Trial and Appellate Courts.

The outcome-dependent one-way strict scrutiny approach taken by the Eleventh Circuit in this case, and by the Third Circuit in *Paoli*, confounds the process of judicial review and disrupts the rational allocation of responsibility between trial and appellate courts. Just two years ago this very issue was addressed in *First Options of Chicago, Inc. v. Kaplan*.[21] The plaintiffs in *Kaplan* had filed suit in Federal District Court, hoping to vacate an arbitration award. When the court confirmed the award they appealed to the Third Circuit, which set it aside.[22] The appellate court exercised plenary review over the trial court's legal determinations, but to the extent factual findings were in dispute, the "scope of review [was] limited to whether those findings [were] clearly erroneous."[23]

On *certiorari* to this Court, the defendant in *Kaplan* took the position that the federal policy favoring arbitration should have controlled the standard under which both legal and factual findings were reviewed. According to the defendant's argument, an especially lenient "abuse of discretion" standard should have applied even as to questions of law "when reviewing district court decisions that confirm (but not those that set aside) arbitration awards."[24] The only support cited for this proposition was an Eleventh Circuit decision, which this Court rejected.

> [T]he reviewing attitude that a court of appeals takes toward a district court decision should depend upon 'the respective institutional advantages of trial and

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[21] 115 S. Ct. 1920 (1995).

[22] *Kaplan v. First Options of Chicago, Inc.*, 19 F.3d 1503 (3d Cir. 1994).

[23] *Id.* at 1509.

[24] *Kaplan*, 115 S. Ct. at 1926.

> appellate courts,' not upon what standard of review will more likely produce a particular substantive result.[25]

The Eleventh Circuit's outcome-based one-way strict scrutiny standard in this case is just a reprise of the approach rejected in *Kaplan*. And it is just wrong. An appellate court reviewing evidentiary rulings on expert testimony should focus on whether the trial judge conducted an adequate inquiry into the reliability and relevance of the testimony, and should defer to the trial court's factual findings. Trial courts are in a much better position than appellate courts to determine such facts, as demonstrated all too well by the Eleventh Circuit's analysis of the expert evidence in this case.

II. THE ELEVENTH CIRCUIT'S ANALYTICAL APPROACH IS A MISAPPLICATION OF *DAUBERT*.

The Eleventh Circuit compounded its erroneous standard of review by seriously misinterpreting and misapplying *Daubert's* core holding that expert scientific testimony must derive from valid scientific reasoning. Because of its one-way strict scrutiny standard, the court was too quick to review the expert testimony, and when it "looked hard" it looked in the wrong place. The District Court found there was no reasoned explanation connecting the studies relied upon by the plaintiffs' two principal experts to the conclusions they reached, but the Appellate Court essentially ignored the lack of connective reasoning and focused almost exclusively on the experts' qualifications and their bald assertions that they had used recognized and accepted procedures and methododolgies. Rule 702, as interpreted in *Daubert*, plainly requires more.

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[25] *Id.* (rejecting position taken in *Robbins v. Day*, 954 F.2d 679 (11th Cir. 1992), and quoting *Salve Regina College v. Russell*, 499 U.S. 225, 231-233 (1991)).

A. *Daubert* Requires an Assessment of an Expert's Reasoning and Methodology.

Like the District Judge in this case, trial courts faced with disputed scientific evidence must undertake "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue."[26] This direct and unequivocal mandate derives from the *Daubert* Court's recognition that science is not a static body of knowledge, but "a process for proposing and refining theoretical explanations about the world that are subject to further testing and refinement."[27]

Thus, to determine if an expert's conclusions constitute admissible scientific knowledge under Rule 702, a court must focus on the reasoning process and methodology through which they were developed and validated, not just the conclusions themselves.[28] This emphasis on the "how and the why" behind a conclusion reflects *Daubert's* clear message that a scientist should not be allowed to venture opinions in court that would not pass muster as valid science outside the courtroom. When scientists evaluate scientific work they require justification in terms of reasoning and empirical support,[29] and under *Daubert* the law requires no less.

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[26] *Daubert*, 509 U.S. at 592-93.

[27] *Id.* at 590 (quoting the brief *amicus curiae* of the American Association for the Advancement of Science and the National Academy of Sciences).

[28] *Id.* at 595.

[29] Frederick Suppe, *Afterword* to THE STRUCTURE OF SCIENTIFIC THEORIES 650 (F. Suppe, ed. 2d ed. 1977) ("[F]ar more of science is concerned with reasoning, argument, and marshaling evidence than with manipulating nature in the laboratory. . . . [A] central and characteristic activity of science is *the use of reason* in the [suggestion, development, and evaluation] of hypotheses and theories.") (emphasis in original).

B. Unlike the District Court, the Eleventh Circuit Failed to Consider the Absence of a Reasoned Explanation for the Experts' Conclusions.

Though the Eleventh Circuit ostensibly recognized that the admissibility of expert opinion testimony depends on the underlying reasoning or methodology,[30] its ruling was based almost exclusively on the experts' qualifications and their factual basis—exactly the kind of legalistic analysis of science that *Daubert* eschewed. The Appellate Court listed the information relied upon by the experts, but its only discussion of methodology or reasoning was the cursory observation that one expert had testified "that his methodology 'has been the basis of diagnosis for hundreds of years,' " and that the other expert had "described his methodology as one 'usually and generally followed by physicians and scientists' " [31]

These self-serving statements about the validity of the experts' methodology do not constitute an explanation of how they reached their conclusions. Indeed, by accepting such statements, the Eleventh Circuit allowed the experts to blur the important distinction between diagnosing *what disease* a patient has and *what caused the disease*.[32] In some cases diagnosis does identify cause; for example, a diagnosis that a child has the measles is also a determination that his or her symptoms were caused by the measles virus. For a chronic disease like lung cancer, however, diagnosis does not establish cause.[33] If it did, the expert testimony in this case would not be at issue.

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[30] *Joiner*, 78 F.3d at 530.

[31] *Id.* at 532.

[32] The decisions doctors typically make relate to determining what disease a patient has and how to treat it, not necessarily to the cause of the disease. William B. Schwartz et al., *Decision Analysis and Clinical Judgment*, 55 AM. J. MED. 459 (1973).

[33] *See, e.g. Cavallo*, 892 F.Supp. at 771 (noting that a fundamental assumption underlying differential diagnosis is that "the final, suspected 'cause' remaining after this process of elimination must actually be *capable* of causing the injury.") (emphasis in original).

The Appellate Court's suggestion that "[o]pinions of any kind are derived from individual pieces of evidence, each of which by itself might not be conclusive, but when viewed in their entirety are the building blocks of a perfectly reasonable conclusion" is certainly correct,[34] but it begs the question of how the building blocks are put together, and why. Merely listing the ingredients for a cake does not explain how to bake it. As the dissent correctly pointed out, "an expert may not bombard the court with innumerable studies and then, with blue smoke and sleight of hand, leap to the conclusion. Instead, the expert must explain how the opinion drawn from each study is acceptable under *Daubert*." [35]

C. Reasoning and Methodology Are Inextricably Linked to Conclusions.

The analytical gap between the studies relied upon by the experts in this case and the conclusions they reached went unaddressed largely because the Appellate Court misunderstood and misapplied this Court's admonition in *Daubert* to focus on principles and methodology rather than conclusions. Because conclusions represent the culmination of scientific reasoning and methodology, the only way to assess validity is to ask how a conclusion was reached, but that does not mean conclusions are completely divorced and separate from the underlying reasoning. Quite the contrary.

Even the *Paoli* decision recognized that if "a judge disagrees with the conclusions of an expert, it will generally be because he or she thinks that there is a mistake at some step in the investigative or reasoning process of the ex-

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[34] *Joiner*, 78 F.3d at 532.

[35] *Id.* at 537.

pert."[36] And as the Ninth Circuit observed in *Lust v. Merrel Dow Pharmaceuticals, Inc.*, "[w]hen a scientist claims to rely on a method practiced by most scientists, yet presents conclusions that are shared by no other scientist, the district court should be wary that the method has not been faithfully applied."[37] In this case the issue should not have been at all difficult. The problem with the expert's reasoning was more its absence than its deficiency. The District Court recognized this logical gap in their testimony and excluded it. The Eleventh Circuit should have affirmed.

CONCLUSION

For the foregoing reasons, CMA urges this Court to reject the Eleventh Circuit's one-way strict scrutiny standard of review and to uphold the broad authority and discretion of trial courts to exclude putatively scientific evidence that does not accord with the reasoning and methodology of science. CMA accordingly prays this Court to reverse the Eleventh Circuit's ruling in this case and to reinstate the District Court's judgment in favor of the Petitioners.

Respectfully submitted,

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May 30, 1997

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[36] *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 746 (3d Cir. 1994), *cert. denied*, 115 S.Ct. 1253 (1995).

[37] 89 F.3d 594, 598 (9th Cir. 1996).

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v.

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Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For the Eleventh Circuit

MOTION FOR LEAVE TO FILE AMICUS CURIAE BRIEF AND AMICUS CURIAE BRIEF OF THE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF THE RESPONDENTS

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MOTION OF ASSOCIATION OF TRIAL LAWYERS OF AMERICA FOR LEAVE TO FILE BRIEF AS AMICUS CURIAE

Pursuant to Rule 37.3(b) of the Rules of this Court, the Association of Trial Lawyers of America ("ATLA") respectfully moves this Court for leave to file the accompanying brief as amicus curiae. Petitioner, through counsel, has consented to the filing of this brief; Respondent has denied consent.

ATLA is a national voluntary bar association whose approximately 50,000 members primarily represent injured plaintiffs in civil actions, and defendants in criminal prosecutions. Due to the increasing importance of scientific evidence in our justice system, trial lawyers regularly face the

issue of admissibility of scientific expert testimony. At the same time, ATLA has committed itself to the preservation of the right to trial by jury guaranteed by the Constitution.

ATLA participated as an amicus curiae in the case of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), where the Court set forth standards of admissibility of scientific evidence. In this case, where the Court is presented with the question of the standard of appellate review of such decisions, similar concerns are present.

ATLA believes that the accompanying brief amicus curiae will assist the Court in addressing this issue. The impact of the Court's decision in this case will clearly extend far beyond the parties themselves. ATLA is particularly concerned that appellate review of rulings excluding expert testimony be sufficiently rigorous to safeguard litigants' right to trial by jury. ATLA has undertaken extensive reasearch into the history and current performance of the jury system and brings a broader perspective to this issue than that of the parties.

For these reasons, the Association of Trial Lawyers of America respectfully moves the Court for leave to file the accompanying brief in this case as amicus curiae.

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IN THE

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AMICUS CURIAE BRIEF OF THE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF THE RESPONDENTS

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AMICUS CURIAE BRIEF OF THE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF THE RESPONDENTS

IDENTITY AND INTEREST OF *AMICUS CURIAE*

The Association of Trial Lawyers of America ["ATLA"] is a voluntary national bar association whose 50,000 members primarily represent injured persons.

A motion for leave to file this brief of amicus curiea has been filed with this Court.[1]

[1] Pursuant to Rule 37.6, Amicus discloses that no counsel for a party authored any part of this brief, nor did any person or entity other than

The question presented to the Court in this case is of overriding importance to civil and criminal trial practitioners. This Court has assigned the role of "gatekeeper" to district courts in cases involving scientific evidence. Because that role necessarily requires judges to determine whether litigants may present crucial scientific evidence to the jury, appellate courts must be able to preserve the role of the jury against overreaching by trial judges.

SUMMARY OF THE ARGUMENT

I. The role of evaluating the credibility and weight of testimony, including that of expert witnesses, is allocated to the jury. Appellate courts have historically and traditionally protected the jury's role when reviewing trial court decisions excluding testimony.

In the context of scientific testimony, courts determining admissibility have examined the methodology underlying an expert's testimony for reliability. It is for the jury, however, to decide whether the conclusions based on satisfactory methodologies are credible or entitled to weight. The Court's decision in *Daubert* preserved the methodology/conclusion distinction as the boundary between the roles of judge and jury.

In this case, the trial judge crossed that boundary. The court excluded the testimony of plaintiffs' experts, not based on assessment of the validity of their underlying methodology or procedures, but because the court did not believe the conclusions drawn by the experts. Reversal by the court of appeals was an appropriate exercise of "abuse of discretion" review.

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amicus curiae, its members, or its counsel make a monetary contribution to the preparation or submission of this brief.

II. The fact that the court of appeals scrutinizes rulings excluding expert testimony more closely than rulings admitting such evidence does not create an impermissible "asymmetry" under the Federal Rules of Evidence. The Rules themselves not only liberalized the admissibility of expert opinion, but several rules are explicitly tilted in favor of admissibility of relevant evidence.

In addition, the consequences of erroneously excluding expert evidence implicate the fundamental right of access to justice. Because scientific evidence has become crucial in many areas, a ruling against admissibility frequently sounds the death knell for a plaintiff's cause of action. Moreover, civil plaintiffs generally do not have access to the numbers of experts readily available to manufacturers and other corporate defendants. Closer scrutiny of decisions to exclude expert testimony is warranted to prevent the courthouse door from being shut in error.

Similarly, erroneous exclusion of expert testimony impinges upon the constitutional right to trial by jury. The Seventh Amendment was designed as a safeguard against overreaching and abuse by federal judges. Where judges serve as "gatekeepers," determining whether scientific evidence may be presented to the jury, effective appellate review is necessary to prevent judges from exceeding the scope of their discretion and usurping the functions of the jury.

III. Our justice system is premised on the ability of jurors to perform their responsibility as factfinder, even in areas of considerable scientific complexity. Arguments against close appellate review of rulings excluding evidence reflect, in part, a lack of confidence in the ability to jurors. Empirical studies, however, demonstrate that these fears are unfounded and that jurors evaluate the weight and credibility of scientific evidence as rationally as judges.

ARGUMENT

I. REVERSAL OF THE DISTRICT COURT'S EXCLUSION OF EXPERT TESTIMONY WAS AN APPROPRIATE APPLICATION OF THE ABUSE OF DISCRETION STANDARD.

A. Appellate Courts Have Traditionally Protected the Role of the Jury to Assess the Weight and Credibility of Witnesses.

One of the few bright lines in American jurisprudence recognizes that courts decide issues of law, while issues of fact are reserved for the jury. From the earliest American cases, the jury's responsibility as factfinder has included the assessment of the weight and credibility of the testimony of witnesses. Appellate courts did not hesitate to reverse exclusions of witnesses that trammelled on this domain of the jury. *See, e.g., Evans v. Eaton*, 16 U.S. 454, 505 (1818); *Crane v. Morris' Lessee*, 31 U.S. 610, 620-21 (1834).

This Court has instructed:

> It is the jury, not the court, which is the factfinding body. It weighs the contradictory evidence and inferences, judges the credibility of witnesses, receives expert instructions and draws the ultimate conclusion as to the facts. . . . Its function is to select among conflicting inferences and conclusions that which it considers most reasonable. That conclusion, whether it relates to negligence, causation, or any other factual matter cannot be ignored.

Tennant v. Peoria & Pekin Union Ry., 321 U.S. 29, 35 (1944). *See also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)("Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of the judge.").

When the witness is proffered as an expert, judges have traditionally ruled on admissibility, reserving to the jury the task of evaluating the testimony's credibility and weight. *See*

9 John H. Wigmore , EVIDENCE IN TRIALS AT COMMON LAW §§ 2549 & 2550, at 639-40 (Chadbourn rev. 1981). *See also*, Development in the Law, *Confronting The New Challenges Of Scientific Evidence*, 108 Harv. L. Rev. 1481, 1510-11 (1995) [Hereinafter "*New Challenges*"]

This Court has explained that "the fundamental premise of our entire system [is] that the purpose of the jury is to sort out the true testimony from the false, the important matters from the unimportant matters, and when called upon to do so, to give greater credence to one party's expert witnesses than another's." *Barefoot v. Estelle*, 463 U.S. 880, 902 (1983).

B. Courts Properly Evaluate the Reliability of the Scientific Methodology Underlying Expert Opinion, But the Weight and Credibility of the Expert's Conclusions Are Matters for the Jury.

1. Appellate Courts Have Distinguished Methodology From Conclusion in Defining the Proper Roles of Judge and Jury.

Prior to the 20th Century, courts generally did not impose greater reliability requirements on expert testimony than on testimony from other witnesses. Jack B. Weinstein, *Improving Expert Testimony*, 20 U. Rich. L. Rev. 473, 474-75 (1986). With the increasing importance of scientific evidence in modern trials, however, courts demanded of expert opinion some indicia of reliability in addition to relevance. *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), "ushered in a new era of judicial regulation of novel scientific evidence." *New Challenges* at 1486.

In exercising this control, both before and after enactment of the Federal Rules of Evidence, courts drew a clear distinction between the methodology relied upon by an expert and the conclusions drawn from that methodology. It was for judges to assess the reliability or "general acceptance" of the scientific tests or methodology relied upon by the expert. Whether the expert's conclusions were credible and

whether they should be given great or little weight was for the jury to decide.

The methodology/conclusion distinction has been applied by courts in a variety of circumstances to preserve the jury's role. For example, in *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir. 1984), where experts of opposing parties relied on essentially the same diagnostic methodology, but differed on the conclusions they drew from test results and other information, the court recognized that it was for the jury to determine which was more credible.

The court in *Hines v. Consolidated Rail Corp.*, 926 F.2d 262, 274 (3d Cir. 1991) ruled expert testimony admissible, stating that "though the expert's opinion could be considered to be 'novel,' it appears that, under the Rule 702 standard, his methods were not."

The Fifth Circuit has addressed this issue on several occasions:

> An expert's opinion need not be generally accepted in the scientific community before it can be sufficiently reliable and probative to support a jury finding . . . . What is necessary is that the expert arrived at his causation opinion by relying on *methods* that other experts in his field would reasonably rely upon in forming their own, possibly different opinions, about what caused the patient's disease.

Osburn v. Anchor Laboratories, Inc., 825 F.2d 908, 915 (5th Cir. 1987). *See also Peteet v. Dow Chemical Co.*, 868 F.2d 1428, 1433 (5th Cir. 1989)(As long as an expert's methodology is well-founded, the nature of the expert's conclusion is irrelevant to admissibility, even if it is controversial or unique). The court reaffirmed its position in *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1111 & n.9 (5th Cir. 1991)(en banc), cert. denied, 112 S. Ct. 1280 (1992), stating that the proper analysis is not whether an expert's conclusion is correct, but "whether in reaching his

conclusion, the witness used a well-founded methodology or mode of reasoning." In such a case, the "jury must be allowed to make credibility determinations and weigh the conflicting evidence."

In *United States v. Bonds*, 12 F.3d 540, 564 (6th Cir. 1993), the court ruled that a method of estimating DNA matches was admissible. Defendant's objection that the study did not account for ethnic substructuring was "a dispute over the accuracy of the probability results" that went to the weight of the evidence rather than to its admissibility. *See also Patrick v. South Central Bell Tel. Co.*, 641 F.2d 1192, 1197 (6th Cir. 1980)(where opposing experts disagreed as to calculations of height of utility wire; "credibility judgments of contradictory testimony" by experts are the province of the jury).

Similarly, the court in *Cella v. United States*, 998 F.2d 418, 426 (7th Cir. 1993), stated that "[a]lthough the expert's conclusion differs from those of the defendant's medical experts, he has utilized an accepted methodology in reaching his conclusion." See also *In re Swine Flu Immunization Product Liability Litigation*, 533 F. Supp. 567, 578-79 (D. Colo. 1980)(expert testimony that vaccine caused Guillain-Barre Syndrome, based on epidemiological studies, was admissible where the methodology used was generally accepted; the fact that the results of the study have not been generally accepted by the medical community goes to weight).

State courts have also employed the methodology/conclusion distinction as a boundary between the roles of judge and jury with respect to scientific testimony. As the District of Columbia Court had occasion to explain, admissibility

> begins -- and ends -- with a determination of whether there is general acceptance of a particular scientific methodology, not an acceptance, beyond that, of particular study results based on that methodology.

Ibn-Tamas v. United States, 407 A.2d 626, 639 (D.C. 1979). Where opposing experts disagree as to how epidemiological and other data should be interpreted it is for the jury to decide the issue. *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100, 1110 (D.C. 1986). *See also Rubanick v. Witco Chem. Co.*, 593 A.2d 733, 747-48 (N.J. 1991) (Adopting "methodology-based" test which looks to "whether the scientific knowledge is sufficiently founded on a sound methodology, leaving the decision to credit the theory to the finder of fact.")

2. This Court's Decision in Daubert Reaffirmed the Methodology/Conclusion Distinction Under Rule 702.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), this Court held that the *Frye* standard did not survive the enactment of the Federal Rules of Evidence. The rigid general acceptance test was "at odds with the 'liberal thrust' of the Rules and their 'general approach of relaxing the traditional barriers to opinion testimony.'" *Id.* at 588 (quoting *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988).) Nevertheless, the Court did insist that "Rule 702 . . . clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify." *Id.* at 589.

At several places in its opinion, the *Daubert* court made it clear that a trial judge exercising this "gatekeeping" function must focus on the methodology underlying the expert's conclusion. For example, "to qualify as 'scientific knowledge,'" under Rule 702, "an inference or assertion must be derived by the scientific method." *Id.* at 590. A "key question" is whether a theory or technique "can be (and has been) tested," that is, its "falsifiability." *Id.* at 593.

In addition, the Court noted that "scientists typically distinguish between 'validity' (does the principle support what it purports to show?) and 'reliability' (does application of the principle produce consistent results?). . . . In a case involving

scientific evidence, evidentiary reliability will be based upon scientific validity." *Id.* at 590 n.9. The distinction between "validity" and "reliability" -- that is, between a scientific test or principle and its application in the particular case -- roughly conforms to the methodology/conclusion distinction. *See* Paul C. Giannelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later*, 80 Colum. L. Rev. 1197, 1201 n. 20 (1980).

"Faced with a proffer of expert scientific testimony," the Court instructed, the trial judge must determine "whether the reasoning or methodology underlying the testimony is scientifically valid." *Daubert*, 509 U.S. at 592-93. When testimony satisfies this empirical validation test, the testimony is admissible even if the witness's conclusion is novel and controversial. Edward J. Imwinkelried, *The Daubert Decision: Frye Is Dead, Long Live the Federal Rules of Evidence*, 29 Trial 60, 64 (Sept. 1993).

Finally, the Court made it unmistakably clear that their discretion as gatekeepers does not extend to evaluating the conclusions an expert may draw based on a scientifically valid principle or procedure:

> The inquiry envisioned by Rule 702 is, we emphasize, a flexible one. Its overarching subject is the scientific validity and thus the evidentiary relevance and reliability of the principles that underlie a proposed submission. The focus, of course, must be *solely on principles and methodology, not on the conclusions that they generate*.

509 U.S. at 594-95 (emphasis added).

Federal courts have correctly viewed *Daubert* as reaffirming the methodology/conclusion distinction. *See Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996)("*Daubert* instructs that the admissibility inquiry focuses not on conclusions, but on approaches . . . "employ[ing] scientifically valid methodologies."). Questions of the accuracy of scientific testing should "be addressed through

determination of the weight to be accorded the testimony, rather than through the threshold determination of admissibility." *Fierro v. Gomez*, 865 F. Supp. 1387, 1395 n.7 (N.D. Cal. 1994). *Cf. In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 746 (3d Cir. 1994)("Plaintiffs are correct, of course, that *Daubert* requires the judge's admissibility decision to focus not on the expert's conclusions but on his or her principles and methodology." The court added, however, that it viewed the distinction as having "limited practical import.").

C. The Court of Appeals Properly Applied the Methodology/Conclusion Distinction Under an Abuse of Discretion Standard in this Case.

The court of appeals in this case did no more than determine that the trial judge exceeded the bounds of its discretion so clearly drawn in *Daubert*.

Robert Joiner alleged that he developed small cell cancer as a result of his exposure to PCBs in the course of his employment servicing electrical transformers. On the crucial issue of whether PCBs do in fact initiate or promote cancer in humans, Joiner proffered the expert testimony of qualified experts. Those witnesses testified based on the results of a number of studies, including tests on mice and epidemiological studies. The district court ruled the testimony inadmissible. *Joiner v. General Electric Co.*, 864 F. Supp. 1310, 1327 (N.D. Ga. 1994)

Although the court of appeals gave a "hard look" under its abuse of discretion standard, see 78 F.3d at 535 (Smith, J., dissenting), the court did not need to look far. The trial judge gave no attention to whether the methodologies relied upon the plaintiffs' experts are scientifically valid means of learning whether a substance like PCBs can cause cancer in humans. Indeed, the judge summarily rejected plaintiffs' attempts to establish the scientific validity of reliance on animal studies,

864 F. Supp. at 1324, or that the epidemiological studies "were conducted in a scientific manner". *Id.* at 1326.

Instead, the trial judge stated:

> Defendants still persuade the court that Plaintiffs' expert testimony would not be admissible. Defendants do this by *attacking the conclusions that Plaintiffs' experts draw* from the studies they cite.

864 F. Supp. at 1322 (emphasis added).

The trial judge proceeded to underscore the perceived deficiencies in the studies relied upon by plaintiffs' experts, noting that there were only two animal studies and that some findings could be characterized as preliminary. Further, the judge pointed out that the epidemiological studies involved a small number of subjects or were not statistically significant or failed to control for certain variables. *Id.* at 1323-26.[2]

These factors would have made for effective cross-examination, refutation and rebuttal by defense counsel arguing that the jury should give little or no weight to the experts' opinions. But they were not appropriate bases for the judge to determine admissibility.

Petitioners expend a great deal of effort to establish that courts generally apply the abuse of discretion or "manifestly erroneous" standard to review decisions on the admissibility of expert testimony. Pet. Br. at 22-23. However, many of the decisions they set forth involve issues of relevancy or qualifications of the expert. *Hamling v. United States*, 418 U.S. 87, 108 (1974), for example, focused on relevance. On the specific issue of the reliability of the scientific testimony, under *Frye* "[g]enerally appellate courts used a de novo standard to review admissibility decisions because they had access to the same information as the trial courts regarding

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[2] With one exception, the district court did not examine the studies themselves, but relied on critiques of the studies provided by defendants. 864 F.Supp. at 1325 n. 27, an exercise of discretion that strikes Amicus as questionable.

the 'general acceptance' of a particular scientific method. *New Challenges* at 1526.[3]

In this case, however, the court of appeals stated explicitly that the "district court's ruling on the admissibility of evidence is reviewed for abuse of discretion." 78 F.3d at 529. The court added that "[b]ecause the Federal Rules of Evidence governing expert testimony display a preference for admissibility, we apply a particularly stringent standard of review to the trial judge's exclusion of expert testimony." *Id.* Nevertheless, the court of appeals did not "substitute[] its own judgment for that of the District Court," as Petitioner claims. Brief for Pet. at 20. Rather, the court clearly focused on whether the trial judge properly performed its responsibility under *Daubert*.

The court explained that, under *Daubert:*

> "it is important for trial courts to keep in mind the separate functions of judge and jury . . . . the gatekeeping responsibility of the trial courts is not to weigh or choose between conflicting scientific opinions, or to analyze and study the science in question in order to reach its own scientific conclusions from the material in the field. Rather, it is to assure that an expert's opinions are based on relevant scientific methods, processes, and data.

[3] Indeed, a number of scholars and commentators advocate de novo review of the reliability decisions of trial judges under *Daubert*. E.g. David L. Faigman, Elise Porter & Michael J. Saks, *Check Your Crystal Ball at the Courthouse Door, Please: Exploring the Past, Understanding the Present, and Worrying About the Future of Scientific Evidence*, 15 Cardozo L. Rev. 1799, 1820-21 (1994); Note, Jay P. Kesan, *An Autopsy of Scientific Evidence in a Post-Daubert World*, 84 Geo. L.J. 1985, 2040-41 (1996).

Amicus suggests, as does the dissenting Judge in this case, that the abuse of discretion standard can easily accommodate the kind of "close scrutiny" engaged in by the court of appeals here. See 78 F.3d at 535-36 (Smith, J., dissenting).

> Trial judges must . . . be careful not to cross the line between deciding whether the expert's testimony is based on 'scientifically valid principles' and deciding upon the correctness of the expert's conclusions. The latter inquiry is for the jury and, therefore, judges may not implicitly factor it into their assessment of reliability.

78 F.3d at 530.

In this case, the court of appeals concluded, "the district court . . . excluded the testimony because it drew different conclusions from the research than did each of the experts." *Id.* at 533. This amounted to an abuse of discretion since, "[a]s *Daubert* makes clear, the district court may not decide whether an expert's opinions are correct, but merely whether the bases supporting the conclusions are reliable." *Id.*

The Solicitor General, as amicus, acknowledges the appropriateness of such a ruling under the abuse of discretions standard. Noting that the court of appeals indicated that "the district court misunderstood its role under Daubert and improperly focused on the proffered experts' 'conclusions' rather than on their 'principles and methodology.' . . . That sort of legal error would be a proper ground for reversal under an abuse-of-discretion standard." Brief for the United States as Amicus Curiae at 26: [4]

This, Amicus submits, is precisely the decision of the court of appeals.

[4] The Solicitor General continued: "We disagree, however, with the court of appeals' view that the district court misunderstood its role in this case." *Id.*

II. CLOSE SCRUTINY OF RULINGS EXCLUDING EXPERT TESTIMONY IS NECESSARY TO EFFECTUATE THE LIBERAL THRUST OF THE RULES OF EVIDENCE, ACCESS TO JUSTICE AND THE CONSTITUTIONAL ROLE OF THE JURY.

Petitioners complain of the court of appeals' application of "a particularly stringent standard of review to the trial judge's exclusion of expert testimony," compared to a more deferential review of a ruling admitting evidence. They argue that this "asymmetrical" approach violates accepted doctrine and *Daubert*. Pet. Br. at 40.

Amicus submits that weighty considerations of policy and constitutional imperative require an appellate standard that favors admissibility. Moreover, there are no countervailing concerns sufficient to mandate less stringent review of trial court rulings.

A. Close Scrutiny of Rulings Excluding Expert Testimony Effectuates the Liberal Thrust of the Federal Rules of Evidence.

Leading evidence scholars have long and vigorously criticized judge-made barriers to the truth-finding function of juries. *See, e.g.*, 3 John H. Wigmore, Evidence §688 (1940); Morgan, *Suggested Remedy for Obstructions to Expert Testimony by Rules of Evidence*, 10 U. Chi. L. Rev. 285 (1943); Paul Rheingold, *The Basis of Medical Testimony*, 15 Vand L. Rev. 473, 475 (1962).

The enactment of the Federal Rules of Evidence in 1975 represents a general abolition of many of these common-law barriers. Albert Jenner, Chairman of the Advisory Committee on the Rules of Evidence explained to Congress:

> The Advisory Committee is especially proud of the rules dealing with expert testimony. This area has become encrusted with a heavy and suffocating layer of technicalities wholly inconsistent with the simple facts of life and the intelligence of American jurors. . . .

> As practical and experienced trial lawyers, we knew and, in fact have long known that intelligent jurors realize that an expert is only stating his opinion, that his testimony is to be treated as an opinion and is not binding upon the jurors and is to be judged in the light of all the evidence in the case, to be accepted or rejected by a juror as he sees fit.

Rules of Evidence, Hearings Before the Special Subcom. on Reform of Federal Criminal Laws of the House Comm. on the Judiciary, 93d Cong., 1st Sess. 87-88 (1973).

Judge Weinstein has declared:

> The Federal Rules of Evidence have produced an enormous loosening up of the restrictions on the admission of expert testimony, on its basis, on its form, and on the effective utilization of such testimony one admitted. This relaxation was needed to give the trier of fact convenient access to the reliable technical knowledge that is available in our modern society.

Jack B. Weinstein, *Improving Expert Testimony*, 20 U. Rich. L. Rev. 473, 482 (1986).

This Court's decisions under the Rules have consistently upheld the Rules' preference in favor of broad admissibility of scientific evidence and confidence in the jury's ability, aided by cross-examination and the adversarial process, to carry out its factfinding function. *E.g., Rock v. Arkansas*, 483 U.S. 44, 61 (1987). In *Daubert*, the Court recognized the "liberal thrust" of the Federal Rules and their "general approach of relaxing the traditional barriers to 'opinion' testimony." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), quoting *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988).

Indeed the Rules themselves prescribe "asymmetrical" standards favoring admissibility, even in areas committed to the sound discretion of the trial judge. Rule 403, for example, provides that relevant evidence may be excluded "if its probative value *is substantially outweighed by* the danger of

unfair prejudice . . ." Rules 803(6) and 803(8) provide exceptions to the hearsay rule for business records and public records "unless the sources of information or other circumstances indicate lack of trustworthiness."

Professor Berger, noting such examples of "presumptively admissible" evidence under the Rules, opined that the "Court's analysis in *Daubert* suggests that scientific expert testimony requires the same treatment - the evidence should be presumed to be admissible until the opponent discharges its burden to show the contrary." Margaret A. Berger, *Procedural Paradigms For Applying The Daubert Test*, 78 Minn. L. Rev. 1345, 1367 (1994).

It cannot be maintained that the notion of preference in favor of admitting expert testimony is inconsistent with the Federal Rules.

B. Close Scrutiny of Rulings Excluding Expert Testimony is Necessary to Preserve Access to Justice.

There are strong policy reasons that warrant closer scrutiny of decisions to exclude expert testimony. Because scientific evidence is often essential to a vindication of legal rights, a trial judge who erroneously rules such testimony inadmissible does not simply exclude a piece of evidence. This is frequently the deathknell of plaintiff's cause of action.

One of this Court's earliest pronouncements declared that "the very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury. One of the first duties of government is to afford that protection." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 163 (1803). This right of access to justice is so fundamental that this Court has located "the duty of every State to provide, in the administration of justice, for the redress of private wrongs" in the Due Process Clause of the Fourteenth Amendment. *Missouri Pacific Ry. Co. v. Humes*, 115 U.S. 512, 521 (1885). *See also Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 429 (1982)("The

Court traditionally has held that the Due Process Clauses protect civil litigants who seek recourse in the courts, either as defendants hoping to protect their property or as plaintiffs attempting to redress grievances.").

This Court's decisions striking down state restrictions on providing legal services to potential plaintiffs have further recognized that "meaningful access to the courts is a fundamental right within the protection of the First Amendment." *United Transportation Union v. State Bar of Michigan*, 401 U.S. 576, 585 (1971).

It is a fact of our justice system today that "in many sorts of civil litigation, the plaintiffs cannot satisfy their burden of proof without scientific evidence." Margaret A. Berger, *Procedural Paradigms For Applying The Daubert Test*, 78 Minn. L. Rev. 1345, 1348 (1994). It is also a fact of life that in any given field of science, most of the qualified experts are employed by, or are engaged in research funded by manufacturers or corporations who are frequent defendants in such litigation. As one court has recognized, undue restrictions on expert testimony place an especially onerous burden on injured plaintiffs, who do not have access to the numbers of experts available to manufacturers. *Knight v. Otis Elevator Co.*, 596 F.2d 84, 88 (3d Cir. 1979).

Close scrutiny of rulings excluding expert testimony is appropriate to prevent judges who set the bar of admissibility too high from preventing aggrieved persons "from resorting to the courts to vindicate their legal rights. The right to petition the courts cannot be so handicapped." *Brotherhood of Railway Trainmen v. Virginia ex rel. Virginia State Bar*, 377 U.S. 1, 7 (1964).

C. Close Scrutiny of Rulings Excluding Expert Testimony is Necessary to Preserve the Constitutional Role of the Jury.

The Seventh Amendment provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of common law.

U.S. Const., amend vii.[5]

The Seventh Amendment is specifically directed at the "otherwise autocratic power and authority of the judge." *Granfinanciera S.A. v. Nordberg*, 492 U.S. 33, 83 (1989) (White, J., dissenting).

Denial of the colonists' right to trial by jury was a primary grievance against the King, ultimately leading them to break free of England. Stephan Landsman, *The Civil Jury In America: Scenes From an Unappreciated History*, 44 Hastings L.J. 579, 595-97 (1993). Specifically, the American colonists complained bitterly of efforts by the Crown to shift the adjudication of civil and criminal disputes from colonial courts, where local juries sat, to Vice-Admiralty courts and other non-jury tribunals. *See* Roscoe Pound, THE DEVELOPMENT OF CONSTITUTIONAL GUARANTEES OF LIBERTY 69-72 (1957)

Strong objections to the absence of an explicit guarantee of the right to trial by jury sparked the Antifederalist demand for a Bill of Rights as a condition to ratification of the Constitution itself. *See* Joseph Story, COMMENTARIES ON THE CONSTITUTION OF THE UNITED STATES 653 (R. Rotunda & J. Nowak eds. 1987)(1833); Edith Guild Henderson, *The Background of the Seventh Amendment*, 80 Harv. L. Rev. 289, 298 (1966); Charles Wolfram, *The Constitutional*

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[5] Congress has restated this guarantee even more forcefully for federal courts:

> The right of trial by jury as declared by the Seventh Amendment to the Constitution or as given by a statute of the United States shall be preserved to the parties inviolate.

Fed. R. Civ. Pro. 38(a).

History of the Seventh Amendment, 57 Minn. L. Rev. 639, 657-59 (1973). Alan Howard Scheiner, *Judicial Assessment of Punitive Damages, the Seventh Amendment, and the Politics of Jury Power*, 91 Colum. L. Rev. 142, 156-60 (1991).

The Antifederalists harbored grave fears that the new national government would necessarily fall under the control of a small elite of moneyed interests. There was no question that the unelected, life-tenured federal judiciary, "unencumbered by juries," would be selected from and would serve that elite against the interests of the people. 3 THE COMPLETE ANTI-FEDERALIST 49 (An Old Whig). Even well-intentioned judges can pose a danger to the rights of common people, the Antifederalists asserted, because judges will frequently have a bias toward those of their own rank. Landsman, *supra*, at 600. The civil jury, therefore, would serve as a bulwark against private as well as public oppression. Scheiner, *supra*, at 152.

The Seventh Amendment's restraint on judicial power continues to be vital. As Judge Patrick Higginbotham points out, "American federal courts . . . have a peculiar need for the democratizing influence of the jury" because an independent judiciary, essential to judicial review, also carries "its attendant risk of autocratic behavior." Patrick Higginbotham, *Continuing the Dialogue: Civil Juries and the Allocation of Judicial Power*, 56 Texas L. Rev. 47, 52 (1977).

For this reason, this Court has historically championed the right to trial by jury and has viewed any infringement with great disfavor.

> Maintenance of the jury as a fact-finding body is of such importance and occupies so firm a place in our history and jurisprudence that any seeming curtailment of the right to a jury trial should be scrutinized with the utmost care.

Dimick v. Schiedt, 293 U.S. 474, 486 (1953). Describing the right to trial by jury as "a great constitutional right", this Court stated that "it is only in exceptional cases and for specific causes that a party may be deprived of it." *Grand Chute v. Winegar*, 82 U.S. 373, 375 (1872). *See also, Lyon v. Mutual Benefit Assoc.*, 305 U.S. 484, 492 (1939) ("It is essential that the right to trial by jury be scrupulously safeguarded").

The gravitational pull of the Seventh Amendment necessarily affects appellate review in federal courts. This Court has cautioned that

> because the federal courts operate under the strictures of the Seventh Amendment. . . . we are reluctant to stray too far from traditional common-law standards, or to take steps which ultimately might interfere with the proper role of the jury.

Browning-Ferris, Indus. v. Kelco, 492 U.S. 257, 279 n.26 (1989).

Amicus submits that erroneous exclusions of scientific evidence, unlike erroneous admissions, may effectively deprive plaintiffs of their right to trial by jury. Closer scrutiny of such decisions is therefore warranted to preserve that constitutional right. See *Ambrosini v. Labarraque*, 101 F.3d 129, 133 (D.C. Cir. 1996)("When a court denies the right to have a jury decide a disputed issue, especially one of a scientific nature, its reasons for doing so must be strong.").

Because the guardianship of the respective roles of judge and jury necessarily falls to the judges themselves, the question arises: Quis custodiet ipsos custodes? -- Who shall guard the guards themselves. Amicus submits that appellate courts must effectively exercise review to ensure that trial judges do not exceed their role.

The Third Circuit recognized this responsibility to scrutinizing decisions of trial judges that, if erroneous, may infringe upon the right to trial by jury:

> [W]here no undesirable or pernicious element has occurred or been introduced into the trial and the trial judge nonetheless grants a new trial on the ground that the verdict was against the weight of the evidence, the trial judge in negating the jury's verdict has, to some extent at least, substituted his judgment of the facts and credibility of the witnesses for that of the jury. Such an action effects a denigration of the jury system and to the extent that new trials are granted the judge takes over, if he does not usurp, the prime function of the jury as the trier of the facts. It then becomes *the duty of the appellate tribunal to exercise a closer degree of scrutiny* and supervision than is the case where a new trial is granted because of some undesirable or pernicious influence intruding into the trial. Such a close scrutiny is required in order to protect the litigants' right to jury trial.

Lind v. Schenley Indus., Inc., 278 F.2d 79, 90 (3d Cir.) (in banc), cert. denied, 364 U.S. 835 (1960)(emphasis added).

Of similar import is Justice Black's caution in *Galloway v. United States*:

> A verdict should be directed, if at all, only when, without weighing the credibility of the witnesses, there is in the evidence no room for honest difference of opinion over the factual issued in controversy. I shall continue to believe, that in all other cases a judge should, in obedience to the command of the Seventh Amendment, not interfere with the jury's function. Since this is a matter of high constitutional importance, appellate courts should be alert to insure the preservation of this constitutional right.

319 U.S. 372, 407 (1943)(Black, J., dissenting). The price of the lack of such vigilance may well be "the 'gradual process of judicial erosion which . . . has slowly worn away a major portion of the essential guarantee of the Seventh Amendment.'" *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 339 (1979)(Rehnquist, J., dissenting), quoting Justice Black in *Galloway*, 319 U.S. at 397.

III. FEARS OF JURY INCOMPETENCE TO ASSESS THE WEIGHT AND CREDIBILITY OF EXPERT TESTIMONY ARE UNFOUNDED.

The reluctance to allow the jury to perform its role in assessing the weight and credibility of expert testimony plainly reflects lack of confidence in the jury.

> In this regard, respondent seems to us to be overly pessimistic about the capabilities of the jury and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.

Daubert, 509 U.S. at 596. *See also Barefoot v. Estelle*, 463 U.S. 880, 899 (1983)("Petitioner's entire argument . . . is founded on the premise that a jury will not be able to separate the wheat from the chaff. We do not share in this low evaluation of the adversary process.")

The Court's confidence is well placed. Recent empirical studies 'strongly rebut[] the broad assumption that jurors are not competent to understand complicated scientific evidence.' Michael S. Jacobs, *Testing the Assumptions Underlying the Debate About Scientific Evidence: A Closer Look at Juror "Incompetence" and Scientific "Objectivity,"* 25 Conn. L. Rev. 1083, 1090, 1094-98 (1993).

Although "[c]oncerns about jury competence preceded the founding of the United States and have troubled scholars and jurors throughout the history of the American judicial system," and "although critics [of the jury system] have succeeded in forging agreement that juries perform poorly in some complex cases," courts, legislatures, and other rulemaking bodies "should consider such critics' reform proposals with skepticism." Developments in the Law – the Civil Jury: The Jury's Capacity to Decide Complex Civil Cases, 110 Harv. L. Rev. 1489, 1491 (1997). That conclusion

– and the Framers of the Seventh Amendment's faith in the competence of juries – is vindicated by modern social science research.

In summarizing five recent social science research projects concerning "jury competence in ordinary trials," Joe S. Cecil, Project Director in the Division of Research at the Federal Judicial Center, and Valerie P. Hans, Professor of Criminal Justice and Psychology at the University of Delaware, concluded that "doubts about jury competence expressed by jury critics stand in sharp contrast to the judgments of scholars who conduct research on jury decisionmaking." Joe S. Cecil, Valerie P. Hans, and Elizabeth C. Wiggins, *Citizen Comprehension of Difficult Issues: Lessons from Civil Jury Trials*, 40 Am. U. L. Rev. 728, 744-45 (1991). Indeed, "empirical evidence consistently points to the general competence of the jury" in such ordinary cases. *Id.* at 745.

Although research results regarding jury competence is more equivocal when juries are confronted with complex questions involving toxic torts, medical malpractice, expert scientific testimony, or complicated economic issues, there is no evidence that lay juries are more perplexed or less competent than lay judges. "[A] juror's evaluation of [complicated] evidence should not be compared to that of an expert in the field. The more likely alternative to the jury is the judge, and judges also fall prey to statistical errors." (footnotes omitted). *Id.* at 764. Researchers found "high rate of agreement between judges and juries" on questions of liability and damages in civil cases. *Id.* at 746.

See also Richard Lempert, *Civil Juries and Complex Cases*, in VERDICT: ASSESSING THE CIVIL JURY SYSTEM 235 (R. Litan ed. 1993) (social science evidence demonstrates that "we cannot assume that judges in complex cases will perform better than juries"); Neil Vidmar, MEDICAL MALPRACTICE AND THE AMERICAN JURY: CONFRONTING THE MYTHS ABOUT JURY INCOMPETENCE, DEEP POCKETS, AND OUTRAGEOUS

AWARDS 175-182 (1995) (summarizing empirical studies on judge-jury agreement in cases involving complex scientific evidence).

Indeed, a Federal Judicial Center study constituting "the first, and to date only, systematic examination of reported performance of jurors across a substantial number of demanding civil trials," "negates the image of bewildered, inattentive juries overwhelmed by complex evidence." Cecil, et al., *Citizen Comprehension*, 40 Am. U. L. Rev. at 750, 751.

See Shari Seidman Diamond and Jonathan D. Casper, *Blindfolding the Jury to Verdict Consequences, Damages, Experts, and the Civil Jury*, 26 Law & Soc. Rev. 513, 557 (1992) ("The evidence . . . is quite inconsistent with the model of the jury as a passive and malleable recipient of testimony. Moreover, even where the testimony is arcane, complex, and difficult to follow, jurors make conscientious and often successful efforts to deal with the substance of what they hear, and their decisions reflect such activity."); Lempert, *Civil Juries* at 234-35; Valerie P. Hans, *The Jury's Response to Business and Corporate Wrongdoing*, 52 Law & Contemp. Pblms. 177, 189 (1989) ("In experimental studies in which mock jurors were presented with scientific and quantitative evidence . . . the presentation of scientific evidence was not ignored, nor did it overwhelm other factors in jurors' judgments.").

In sum, "the overall picture of the jury that emerges from available data indicates that juries are capable of deciding even very complex cases. Cecil, et al., Citizen Comprehension, 40 Am. U. L. Rev. at 764.

Even recognizing the limitations of both judges and juries, prudence suggests that the jury is the preferable arbiter. Jury decisions do not become precedents -- "when a court makes a scientific mistake, the consequences are far broader than if a jury makes the same mistake." Anthony Z. Roisman,

Conflict Resolution In The Courts: The Role Of Science, 15 Cardozo L. Rev. 1945, 1949 (1994).

Amicus suggests that the opportunities for improving juror understanding and performance have not been exhausted. Effective appellate review to protect the jury's role as factfinder continues to be appropriate, both as public policy and constitutional imperative.

CONCLUSION

For the foregoing reasons, Amicus Curiae urges this Court to affirm the judgment of the Court of Appeals.

Respectfully submitted,

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No. 96-188

(18)

In The
Supreme Court of the United States

October Term 1996

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,

v.

ROBERT K. JOINER, *et al.*,
Respondents.

**ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT**

MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE*, AND BRIEF FOR ARDITH CAVALLO AS *AMICUS CURIAE* SUGGESTING AFFIRMANCE

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IN THE

Supreme Court of the United States

OCTOBER TERM 1996

No. 96-188

GENERAL ELECTRIC CO., *et al.*,
Petitioners,

v.

ROBERT K. JOINER, *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Eleventh Circuit

MOTION OF ARDITH CAVALLO FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* SUGGESTING AFFIRMANCE

Ardith Cavallo, petitioner in Case No. 96-1493, respectfully moves that she be permitted to file a brief *amicus curiae* suggesting affirmance in this case. Mrs. Cavallo has an interest in the outcome of this case.[1] She is petitioner in No.

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[1] A more detailed statement of Mrs. Cavallo's interest is set forth in the Interest of *Amicus Curiae* section of the brief.

96-1493, *Cavallo v. Star Enterprise, et al.*, which presents the same major issue as this case, and which was filed on March 19, 1997, two days after the Court granted *certiorari* in this case. *Cavallo* is pending. If this case is affirmed it would, at a minimum, support a remand of *Cavallo* to the court of appeals for consideration under a different and far less deferential standard of review.

The 19 page brief *amicus curiae* presents a concise argument highlighting major reasons the Eleventh Circuit's decision in this case should be affirmed. We believe the brief will be helpful to the Court.

A letter of consent to the filing of this brief has been obtained from counsel for Petitioners and has been filed with the Clerk. Respondents have withheld consent.[2]

Respectfully submitted,

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[2] As stated in footnote 1 of the brief, no counsel for any party has authored all or any part of the brief. The only persons who have made any financial contribution to the brief or its preparation are Ardith Cavallo and her husband, Lawrence Cavallo.

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IN THE

Supreme Court of the United States

OCTOBER TERM 1996

No. 96-188

GENERAL ELECTRIC CO., *et al.*,
Petitioners,

v.

ROBERT K. JOINER, *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Eleventh Circuit

BRIEF FOR ARDITH CAVALLO AS *AMICUS CURIAE* SUGGESTING AFFIRMANCE

INTEREST OF *AMICUS CURIAE*

Ardith Cavallo is petitioner in *Ardith Cavallo v. Star Enterprise, et al.*, No. 96-1493, which was docketed March 20, 1997, and is pending.[1] *Cavallo v. Star Enterprise* seeks

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[1] Petitioners' letter of consent to the filing of this brief has been filed with the Clerk. Respondents have refused consent. No counsel for a party has authored this brief in whole or part, and no person other than Mrs.

review of that part of the judgment of the United States Court of Appeals for the Fourth Circuit[2] which affirmed the district court's exclusion of expert scientific testimony as to the causes of Mrs. Cavallo's illnesses.[3] The exclusion, based on the grant of an *in limine* motion, resulted in a summary judgment for the defendants. The proffered expert testimony in *Cavallo* was that of a well credentialed toxicologist, Dr. David Monroe, and of Mrs. Cavallo's treating physician, Dr. Joseph Bellanti, an internationally prominent physician who heads the Department of Allergy and Immunology at Georgetown Medical Center. He employed the accepted technique of "differential diagnosis" to determine the etiology of Mrs. Cavallo's health problems, which began following exposure to fumes from a release of aviation jet fuel, negligently spilled by the defendants in that case.[4]

The Fourth Circuit applied the most highly deferential abuse of discretion standard of review to affirm district court rulings applying *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), in such manner that the court of appeals termed the exclusions "close", and the district court's interpretation "restrictive." The court of appeals found no abuse of discretion in the district court's interpretation of *Daubert* as limiting the admissibility of expert scientific testimony beyond the strictures of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

Mrs. Cavallo has an interest in the outcome of the instant case because a decision by the Court in favor of Respondents would, at a minimum, support a remand to the court of appeals to review the district court *Cavallo* rulings under a different and far less deferential standard of review.[5]

SUMMARY OF ARGUMENT

The purpose of this brief is not to present detailed arguments and voluminous citation of authority. Rather, we set forth the reasons we believe most compelling in support of affirmance. The question of the correctness of district court *Daubert* rulings approaches being a question of law which the court of appeals efficiently and effectively can decide on the record.

Cavallo and her husband, Lawrence Cavallo, made any monetary contributions to its preparation or submission.

2 100 F.3d 1150 (1996), *petition for certiorari filed*, 65 U.S.L.W. 3666 (1997).

3 892 F.Supp. 756 (E.D. Va. 1995).

4 *See Cavallo* petition at 2-3.

5 As stated in the *Cavallo* petition at 4-5, n.13 at 12-13; Reply to Br. in Op. at 7-8, *Cavallo* should be reversed regardless of the standard of review because the district court ruled based on a misunderstanding of *Daubert*. In *Cavallo*, we stated the Question Presented as "Whether . . . the Fourth Circuit erroneously applied the most highly deferential abuse of discretion standard of review." We maintain that the standard of review applied should not have been highly deferential abuse of discretion. However, even were that the correct standard, the Fourth Circuit misapplied it.

The standard of review should produce uniformity of results, and predictability in the law. Uniformity discourages institution of cases that cannot pass informed scrutiny and encourages voluntary resolutions of those that can.

Whether a proposed scientific expert followed acceptable methodology cannot be left to the individual discretion of "hundreds of district judges" whose decisions on the issue are subject only to a highly deferential abuse of discretion standard of review. The standard of review should strictly scrutinize exclusion of expert scientific testimony since the Federal Rules of Evidence show a preference for admissibility. The review must be based on whether likely result determinative evidence should have been admitted. However, if the court of appeals makes a preliminary determination that the evidentiary ruling clearly would not have affected the result of the case, it need examine no further.

The lower courts have misconceived the scope and depth of the "gatekeeping" inquiry required by *Daubert*. *Daubert* did not contemplate that district judges would screen and evaluate scientific methodology in excruciating detail. All that was intended is a demonstration that the scientific expert's conclusions are based on application of scientific method and knowledge. Claimed gaps in methodology go to the weight and credibility of the testimony, not its admissibility.

Daubert did not intend mini-trials, even mini-trials on papers. Detailed methodological analysis needlessly and inappropriately consumes judicial resources at both the trial and appellate levels. The role of the trial judge should be only to keep speculation and conjecture from the jury, not to insulate the jury from evidence from reputable scientific sources.

With a limited inquiry, courts of appeals easily can determine whether *Daubert's* requirements have been satisfied. A detailed analysis of methodologies increases the

burden on a reviewing court for those cases appealed. Moreover, a highly deferential abuse of discretion standard of review does not discourage appeals. The detailed inquiry, especially when combined with a highly deferential standard of review, simply increases appellate burdens. Furthermore, a single standard of review favoring admissibility has instructive value for the district courts. Additionally, detailed inquires and rulings by courts have greater and more far reaching impact than a single jury verdict. Judicial mistakes by "amateur scientists" survive and are likely to produce more incorrect results. That is far less likely with an isolated, incorrect jury verdict.

The policy preferring admissibility of evidence does not conflict with the policy of favoring the grant of summary judgment in an appropriate case. The questions of admissibility and whether there is a triable issue of material fact are separate and distinct. The Federal Rules of Evidence do not support excluding evidence so that summary judgment can be granted. Exclusion is the remedy least favored by the Rules.

A highly deferential abuse of discretion standard of review produces nonuniform, inconsistent, and unpredictable results. Cases are difficult to reconcile, and the decisions provide little guidance for the district courts. A review favoring admissibility and looking closely at exclusions produces more uniform and consistent results. Such rulings create not only uniformity, but predictability in the law, and are more useful to the lower courts.

ARGUMENT

TRIAL COURT RULINGS REGARDING ADMISSIBILITY OF EXPERT SCIENTIFIC TESTIMONY SHOULD BE REVIEWED PURSUANT TO A LEGAL STANDARD FAVORING ADMISSIBILITY

A. Introduction

Our purpose is not to repeat at length the arguments and citation to authority that likely will be made by Respondents, and other *amici*. Rather, we present in abbreviated form what we consider the most compelling reasons the question of whether result determinative expert scientific testimony is admitted cannot be left virtually to the complete discretion of individual district judges. The issue of the acceptability of methodology employed by experts whose qualifications are impeccable is, or approaches being, a question of law. Whether characterized as a matter of law, or something akin thereto, the determination of the correctness of the district court decision is something the courts of appeals can decide as effectively on the record as can the trial court.

B. The Standard of Review Should Be Uniform and Neutral, Resulting in Not Merely a "Reasonable", But a Legally Correct Result

While we recognize that absolute uniformity of result on the same, or substantially identical, facts is an ephemeral and illusive goal impossible of achievement, nonetheless, it is a goal the judicial system seeks. That being so, the standards for admissibility of expert scientific testimony must be determined on a circuit-wide basis, and not on the

particular view points of "hundreds of district judges." *Daubert*, *supra*, 509 U.S. at 600 (Rehnquist, C.J., dissenting). There inevitably will be conflicts within the circuits, and among the circuits. However, there are mechanisms for resolution of the intra-circuit conflicts, and, if inter-circuit conflicts become serious enough, this Court may need to resolve them.

Uniformity is not merely an intellectual and abstract end. Its primary purpose is to achieve predictability in the law -- a result that also serves the goal of judicial economy by discouraging institution of cases that cannot pass informed scrutiny, and encouraging voluntary resolutions of those that can.

The circuit that decided *Paoli,*[6] and the Eleventh Circuit in the instant case, recognized correctly that the question of whether a proposed scientific expert followed acceptable methodology to make his/her opinion reliable enough to be admissible cannot be subject to the same highly deferential standard of review as other evidentiary rulings. Thus, while terming the standard of review a deferential one, the deference accorded by those circuits is less than in other evidentiary matters.[7]

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[6] *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994), *certorari denied sub nom. General Electric Co. v. Ingram,*__U.S.__, 115 S.Ct. 1253 (1995).

[7] The difference between the "hard look" or a "stringent standard or review" these courts mention and *de novo* review is a matter of degree. The "hard look"/"stringent standard" gives a slight degree of deference to the trial judge, whereas *de novo* review gives none. *Cf. Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 385, 401 (1990), stating that "the abuse of discretion and clearly erroneous standards are indistinguishable." In any event, the discretion exercised by district courts must be with a view that favors admissibility of evidence. *Cf. Ambrossini v. Labarraque*, 101 F.3d 129, 131 (D.C. Cir. 1996), *petition for certiorari dismissed sub nom. Upjohn Co. v. Ambrossini*, 65 U.S.L.W. 3755 (1997) (court must have

The short answer is that a trial judge should not have highly deferential discretion to determine the outcome of a case by ruling upon a matter an appellate court is in as good a position to decide as is the trial judge. While a highly deferential abuse of discretion standard of review necessarily has its place, such review should be confined to those instances where the trial judge is in fact in a far superior position to make a judgment, and where a cold record cannot provide the same vantage point for an appellate court. *See, e.g., Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 385 (1990).

In *Daubert*, the Court held that the *Frye* "general acceptance" test of admissibility of expert scientific testimony was superseded by the Federal Rules of Evidence. The Court noted the liberal thrust of the Federal Rules, which display a preference for admissibility. However, the Court did not address the issue of the standard of appellate review applicable to district court *Daubert* rulings.[8]

As the Third Circuit noted in *Paoli,* and as the Eleventh Circuit stated in this case, the Federal Rules of Evidence evince a preference for admissibility. 35 F.3d at 750; C.P.A. at 4.[9] *Compare, Daubert,* 509 U.S. at 596, stating that "vigorous cross-examination, presentation of contrary evidence, and careful [jury] instruction on the

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strong reasons for declining to let jury decide dispute, especially one of scientific nature).

[8] The Ninth Circuit held in its 1991 *Daubert* decision that the question of reliability under *Frye* should be reviewed *de novo*. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128, 1130 (9th Cir. 1991). On remand from this Court, the Ninth Circuit again proceeded on a *de novo* basis. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1314-1315 (9th Cir. 1995), *certiorari denied*, __U.S.__, 116 S.Ct. 189 (1995). This Court's *Daubert* decision did not direct change in the standard of review applied by the Ninth Circuit.

[9] "C.P.A." references are to the Appendix to the Petition for a Writ of Certiorari.

burden of proof" are to be preferred to "wholesale exclusion under an uncompromising `general acceptance' test", and that "respondent [defendant below] seems to be overly pessimistic about the capabilities of the jury." *And see, Id.*, at 587, 589, noting the FRE's "liberal" standard of relevance, and "the Rules' permissive backdrop." *Cf. Barefoot v. Estelle,* 463 U.S. 880, 900-901 (1983) ("[i]f [the experts] are so obviously wrong . . ., there should be no insuperable problem [discrediting them]", and "the adversary process [can] be trusted to sort out the reliable from the unreliable evidence").

The standard of review must be neutral. That is to say, admission of scientific evidence that results in a judgment against a defendant should be examined under the same standard as applied to exclusion, but with the criterion in mind that exclusion is the least favored remedy. Exclusion of a defense expert should be subject to careful scrutiny. The courts must stand in a neutral posture. There must be guidelines for district judges, and the appellate courts must take a "hard look" at exclusionary evidentiary rulings that likely are result determinative.

As stated above, the courts of appeals are as well equipped to make the determinations as are the district judges. Evidentiary rulings on scientific evidence must not be simply reasonable; they must be legally correct. The Eleventh Circuit in the case at Bar stated just such a standard (C.P.A. at 4):

> we apply a particularly stringent standard of review to the trial court's exclusion of expert testimony.

C. *Daubert* Hearings Should Be Narrow and Based on General Principles

A substantial part of the problem emanates from the lower courts' interpretations of the requirements of *Daubert*. For example, in *Cavallo v. Star Enterprise*, *supra*, the district court believed *Daubert* required it to take a more detailed look at the proposed expert scientific testimony than would have been mandated under *Frye*, stating (892 F.Supp. at 774) (emphasis added):

> Prior to *Daubert*, courts presented with this situation may have been more inclined to admit the expert testimony and allow the jury, aided by vigorous cross-examination, to sort out the relative reliability of opposing expert opinions. But *Daubert* recognized the danger in this approach. * * * *Daubert assigned district courts a more vigorous role to play in ferreting out expert opinion based on the scientific method.*

The Fourth Circuit, while claiming to recognize that *Daubert* was a "liberalization, not a tightening, of the rules controlling the admission of expert testimony" (100 F.3d at 1158), affirmed the district court's detailed analysis of methodology on an issue it called "close", and an approach by the district court that the Fourth Circuit termed "restrictive ..., but ... not inconsistent with *Daubert*" (100 F.3d at 1159).

Daubert did not contemplate that trial judges would scrutinize each and every step of scientific methodology. All that was intended is that it be demonstrated that the expert based his or her conclusion on the application of scientific knowledge and method. That is what the Court meant when

it stated that "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional means of attacking shaky but admissible evidence" (509 U.S. at 596). In other words, if there is a gap in, or question about, application of the methodology, such goes to the credibility or weight of the testimony. *It does not go to its admissibility. See Compton v. Subaru of America, Inc.*, 82 F.3d 1513, 1518 (10th Cir. 1996); *Jones v. Otis Elevator Co.*, 861 F.2d 665, 663 (11th Cir. 1988). The opponent of the evidence can attack the claimed deficiencies in cross-examination, and can produce contrary evidence, including evidence that the scientific methodology was followed inadequately, and can challenge the underlying "scientific knowledge" on which an expert opinion is based. *See* E.J. Imwinkelried, "Coming to Grips with Scientific Research in *Daubert's* `Brave New World'", 61 Brooklyn L. Rev. 1247, 1253 (1995) ("liberalizing admissibility standards . . . shift[s] the focus to the weight of scientific testimony", and "opponent can proffer studies documenting weaknesses in the underlying technique").[10]

We do not believe the Court intended in *Daubert* to require that mini-trials (even on papers) be conducted in which the trial judge is to examine methodology in excruciating detail, and to have exclusionary rulings subject only to a highly deferential abuse of discretion standard of review. Such exacting analysis of methodologies contemplates tremendous expenditures of both litigants' and judicial resources.[11] Thus, we believe the intent of *Daubert*

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[10] The situation is not unlike challenging eye-witness testimony. For example, a witness who claims to have seen an event might be asked if he wears glasses and whether he was wearing them. Whether he was or not does not go to admissibility. It goes to credibility and weight. In the same way a deviation from exact methodology may make the testimony "shaky", but it does not make it inadmissible.

[11] *Cf. Daubert*, 509 U.S. at 600-601 (Rehnquist, C.J., dissenting):

was to assign to the district judges a gatekeeping role to keep totally unsupported speculation out of the courtroom. However, *Daubert* was not intended to require district judges to do minute screening of basically reputable scientific evidence from reputable sources. *Cf. Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1124-1125 (9th Cir. 1994) (record reflects opinions based on scientific data and techniques "relied on by medical experts in making determinations regarding toxic causation where there is no solid body of epidemiological data", and this "satisfied the requirements established in *Daubert*"). *Daubert's* intent was only to preclude *"[c]onjectures . . . of little use"* (509 U.S. at 597, emphasis added). *See* C.P.A. at 7 (gatekeeping role is simply to guard jury from pure speculation).[12]

> I do not doubt that Rule 702 confides to the judge some gatekeeping responsibility in deciding questions of the admissibility of proffered expert testimony. But I do not think it imposes on them either the obligation or authority to become amateur scientists in order to perform that role.

And see Brief of the Solicitor General at 15 (hereafter, "S.G. Br.") (emphasis added):

> No judge may be presumed to have pre-existing familiarity with whatever principles, techniques, or other technical background material may be relevant to the scientific evidence offered in a particular case. *The district court must expend whatever resources are necessary to achieve sufficient familiarity to discharge its responsibilities under Rule 702.*

[12] That the intent was to preclude only speculation or "conjectures" is further support by the definition of relevance in FRE Rule 401 -- "'Relevant evidence' means any evidence having a tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." "Scientific evidence" does not deal with certainties. Thus, an expert opinion usually cannot conclusively establish a fact. The evidence is

Limiting the scope and depth of the *Daubert* inquiry obviates the concerns expressed by Petitioners at pages 38-40 of their brief. Courts of appeals easily can determine whether the basic requirements of *Daubert* have been satisfied. Indeed, the microscopic analysis advocated by Petitioners, regardless of the standard of review, places a heavy burden on a conscientious appellate court. As Petitioners point out (Br. at 44-45), application of a highly deferential abuse of discretion standard of review does not insulate trial court decisions from appellate review. The more detailed the mandated *Daubert* screening, the greater the work required at the trial and appellate levels, and the more judicial resources are consumed. The appellate burden simply is not lessened by a highly deferential abuse of discretion standard of review.

D. A Highly Deferential Abuse of Discretion Standard of Review for *Daubert* Rulings Will Not Lessen Appellate Burdens; It also Is Inconsistent With an Appeal of Right

There is no evidence that a highly deferential abuse of discretion standard will significantly discourage appeals of

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relevant and should be admitted if it *tends* to make the existence of a material fact more or less probable. It is difficult to reconcile the demand for near certainty of scientific evidence in a civil case with the Court's decision in *Barefoot v. Estelle, supra*, which held proper admission for jury consideration psychiatric testimony, correct only one third of the time, to support imposition of the death penalty with a requirement that litigants in a civil case must meet a higher standard. While *Barefoot* was decided on Constitutional grounds, the anomaly remains. Especially is that so since expert testimony generally is only one item, albeit usually a critical item, in a civil party's proof. *See also* pp. 8-9, *supra*.

district court *Daubert* rulings, as evidenced by the numbers of post-*Daubert* and State cases cited in Petitioners' brief -- cases in circuits or jurisdictions reviewing highly deferentially for abuse of discretion. Most of the cases in which detailed hearings are conducted usually are complex and involve potentially large economic consequences. Moreover, as Petitioners point out (Br. at 38-39), the *Daubert* rulings under a detailed screening often are case specific. A highly deferential abuse of discretion standard of review encourages appeals of such case specific rulings much more than simply a required application of general principles, appropriate "liberal" admission of evidence (as contemplated by the Federal Rules of evidence), trial and a jury verdict.

A highly deferential abuse of discretion standard of review with respect to an issue an appellate court is equally well positioned to decide also is inconsistent with the appeal of right from the district court to the court of appeals.[13] Most rulings, including statutory construction, and even Constitutional questions, are, at least to some extent, case specific. Yet, such rulings are not subject only to a narrow abuse of discretion standard of review.

The argument that analysis by the courts of appeals of the application of established criteria to district court *Daubert* rulings does not have instructive precedential value is disingenuous. Indeed, the Solicitor General seems to recognize this (S.G. Br. at 20-21), as well as the problems inherent in the highly deferential standard of review, suggesting that if an appellate court determines an issue of admissibility "for proceedings within its jurisdiction [is] a

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[13] The courts of appeals certainly function to deal with precedent setting matters. However, they also have the obligation to review "routine" cases for error. That is the purpose of the "Unpublished Opinion." If the appeal of right is to be eliminated, the decision to do so is a legislative function.

recurrent issue involving the admissibility of scientific evidence", a different, more searching, and less deferential standard of review is appropriate.[14] It also highlights that judicial pronouncements are much more far reaching and long-lived than a jury verdict in a particular case. Thus, a judicial mistake by a court engaged in "amateur science" survives and is likely to spawn more incorrect results than is an isolated, incorrect jury decision. *See* A. Z. Roisman, "Conflict Resolution in the Courts: The Role of Science", 15 Cardozo L. Rev, 1945, 1949-1950 (1994) (juries' "mistakes die with the particular case", whereas, "[p]ronouncements by federal judges about what is and is not 'good science' . . . carry many others with them", and that "consequences [of judicial mistakes] are far broader").

E. The Policy Favoring Admissibility of Evidence, and the Policies of Rule 56 of the Federal Rules of Civil Procedure Are Separate and Distinct, and Do Not Conflict

FRCP Rule 56 is separate and distinct from the Federal Rules of Evidence. Petitioners' suggestion (Br. at 42-44) that something other than a highly deferential abuse of discretion standard of review for district *Daubert* rulings undermines FRCP Rule 56 is invalid. The argument confuses the question of admissibility of evidence with determining whether there is a triable issue of material fact.

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[14] The Solicitor General does not explain how courts are to know and determine what cases qualify for "special consideration." Furthermore, rather than a universally applicable standard of review, it would create a two-tiered standard, injecting confusion into the review process. Adoption of such an approach would make law in this area almost entirely unpredictable, creating a judicial "free-for-all" and a litigation nightmare. There must be a single standard of review, not a standard of review determined on a case by case basis.

Daubert mentioned the distinction stating that "in the event the trial court concludes that the scintilla of evidence presented supporting a proposition is insufficient to allow a reasonable juror to conclude that the proposition more likely than not is true, the court remains free to direct a judgment, . . . and likewise to grant summary judgment" (509 U.S. at 596). Nothing in the Federal Rules of Evidence supports Petitioners' argument that exclusion of evidence is to be favored if it will result in a summary judgment.[15] On the contrary, as stated above, *Daubert* states that exclusion is the *least favored* remedy.[16]

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[15] Petitioners' concern emanates from the Third Circuit's statement in *Paoli* (35 F.3d at 750) "that when the district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment, we will give them a 'hard look' to determine if a district court has abused its discretion in excluding evidence as unreliable." The concern is unwarranted. The just quoted statement is followed by footnote 21 stating that in appropriate circumstances, the district court remains free to grant summary judgment. The *Paoli* court was addressing only the admissibility question. In our view, the standard of review for admission or exclusion of expert scientific testimony should be the same whether an appeal is taken from a judgment based on claimed erroneous admission or exclusion. We believe the Third Circuit's statement was based on a recognition that a substantial number of appeals taken on this issue have been from exclusion of the plaintiff's proffered expert scientific testimony. A single standard of review for *Daubert* rulings better serves both the goals of uniformity and of equity of results. *The standard of review must favor admissibility.* Of course, if the reviewing court determines preliminarily that the evidentiary ruling at issue clearly was not result determinative, its inquiry need proceed no further.

[16] It has been argued that the more stringent and detailed the standards for determining admissibility under Rule 702, the more summary judgments will be granted for defendants where liability is predicated on exposure to an allegedly toxic substance. This is so, it is claimed, because it is the plaintiff who has the burden of proof, and because without expert testimony demonstrating causation, the plaintiff's case will fail. Whether or not this is so, we do not suggest a "'free-for-all' in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions"

F. The Highly Deferential Abuse of Discretion Standard of Review Produces Inconsistent, Conflicting, and Unpredictable Results

The highly deferential abuse of discretion standard of review does not produce uniform and predictable results. The cases are difficult, if not impossible, to reconcile. They provide no effective guidance to the district courts.

In *Cavallo v. Star Enterprise, supra*, the district judge excluded a treating physician's testimony based on the established technique of differential diagnosis to determine the cause of Mrs. Cavallo's health problems. The Fourth Circuit affirmed that ruling as a permissible exercise of discretion, not inconsistent with *Daubert*. However, there is no evidence that *Daubert* intended to vest trial courts with this kind of discretion.

While "differential diagnosis" may not be "science in the narrow positivist sense specified in *Daubert*", it is inconceivable that "the Supreme Court could . . . have meant to exclude medical testimony based on differential diagnosis." J.M. Conley and D.W. Peterson, "The Science of Gatekeeping: The Federal Judicial Center's New *Reference Manual on Scientific Evidence*", 74 N.C. L. Rev. 1183, 1203 (1996). *See Paoli, supra*, 35 F.3d at 758-760, upholding the validity of differential diagnosis, and stating that "a doctor does not always have to employ all of these techniques [of differential diagnosis] in order for the doctor's differential diagnosis to be reliable" (*Id.* at 759). *And see* C.P.A. at 10-11. *See also Compton v. Subaru of America, Inc., supra*, 82

(*Daubert*, 509 U.S. at 595-596). However, the potential for skewing results is a matter that deserves more than a passing glance by appellate courts asked to review exclusion of scientific expert testimony where the ruling is result determinative. *See* Roisman, *supra*, 15 Cardozo L. Rev. at 1956-1957, maintaining the argument mentioned above lacks validity.

F.3d at 1517 ("application of *Daubert* factors is unwarranted in cases where expert testimony is based solely on experience or training"). The Fourth Circuit, in *Cavallo*, affirmed exclusion of testimony based on differential diagnosis even though the district court found nothing lacking in the methodology of the differential diagnosis performed by Dr. Bellanti, the treating physician. *See* 100 F.3d at 1158-1159, 892 F.Supp. at 770-773.

Unlike the Eleventh Circuit in the case at Bar, the Fourth Circuit affirmed as a permissible exercise of discretion the district court's rejection of toxicological testimony as to the effects of the jet fuel vapors on Mrs. Cavallo. The district court refused to accept extrapolations from different levels of exposure to volatile organic compounds in the studies on which he relied. It also held his reliance on those studies improper because they did not specifically involve aviation jet fuel, but only a number of the compounds contained in jet fuel. Additionally, it dismissed his conclusions regarding the sensitizing effects of exposure to the chemicals because some of the studies cited were "controversial" and, more importantly, *did not specifically establish a link between the illnesses and aviation jet fuel*. *See* 892 F.Supp. at 768-769. Thus, the district court required studies showing effects of exposure to precisely the same product, not simply the compounds in that product.

The Fourth and other circuits, both before and after *Daubert* consistently have held that an epidemiological study need not involve precisely the exposures claimed to justify scientific opinions based on extrapolation. The *Cavallo* decision conflicts, for example, with the Fourth Circuit's decisions in *Benedi v. McNeil - P.P.C., Inc.*, 66 F.3d 1378, 1384 (4th Cir. 1995) ("we do not read *Daubert* as restricting expert testimony to opinions that are based solely on epidemiological data"); and *City of Greenville v. W.R. Grace Co.*, 827 F.2d 975, 980 n.2 (4th Cir. 1987) (extrapolation

from effects of high levels of exposure to low levels permissible, and liability need not wait until people actually get sick from low level exposure). It also is a odds with *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1535 (D.C. Cir. 1984) ("a cause and effect relationship need not be clearly established by epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists"); and *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741 745 (11th Cir. 1986), ("Plaintiffs' burden . . . did not necessarily require them to produce scientific studies showing a statistically significant association . . . [of] malformations in a large population").

The above demonstrates that the highly deferential abuse of discretion standard of review is unworkable for review of *Daubert* rulings. Litigants cannot predict likely outcomes. Results are inconsistent and confusing.

CONCLUSION

The decision of the Eleventh Circuit should be affirmed. As part of that affirmance, this Court should clarify the scope and depth of the *Daubert* inquiry, making plain, as we believe *Daubert* intended, that the only purpose of judicial "gatekeeping" under FRE Rule 702 is to keep speculation and conjecture out of the courtroom.

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Supreme Court of the United States

October Term, 1996

GENERAL ELECTRIC COMPANY, *et al.*,

Petitioners,

vs.

ROBERT K. JOINER and KAREN P. JOINER,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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INTEREST OF THE *AMICUS CURIAE*[1]

Trial Lawyers for Public Justice ("TLPJ") is a national public interest law firm that specializes in precedent-setting and socially significant civil litigation and is dedicated to pursuing justice for the victims of corporate and governmental abuses. Litigating throughout the federal and state courts, TLPJ prosecutes cases designed to advance consumers' and victims' rights, environmental protection, product safety, civil rights and civil liberties, access to our civil justice system, and the protection of the poor and the powerless.

TLPJ acknowledges and supports the role of trial judges in ensuring the integrity of the court system by screening scientific expert testimony for threshold admissibility purposes. TLPJ is concerned, however, that the limited "gatekeeping" function assigned to trial judges by this Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) has been misinterpreted and misapplied by some district courts to prohibit juries from considering reliable and relevant expert testimony. TLPJ is concerned that, in performing the inquiry required by *Daubert*, a number of trial judges — with the encouragement of opponents of the admission of scientific evidence such as Petitioners and their *amici* — have assumed the roles of jurors and "amateur scientists" in rejecting expert testimony with which they disagree, effectively barring the victims of mass torts and toxic exposures from the courthouse.

Although the question before this Court is the appropriate

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1. Pursuant to Rule 37.6 of the Rules of the Court, counsel for a party did not author this brief in whole or in part and no person or entity, other than the *amicus curiae*, its members, or counsel, have made a monetary contribution to the preparation or submission of the brief. Pursuant to Rule 37.3 of the Rules of the Court, the parties have consented to the filing of this brief. Their letters of consent have been filed with the Clerk of the Court.

standard of appellate review of district court decisions excluding scientific testimony under *Daubert*, Petitioners and their *amici* argue at length for a drastically restrictive and self-serving interpretation of the *Daubert* principles. They effectively urge adoption of a new heightened standard for the admissibility of expert scientific testimony. TLPJ submits this brief for the purpose of responding to the erroneous interpretation of the *Daubert* standards advanced by Petitioners and their *amici*. TLPJ urges the Court to re-emphasize the limited "gatekeeping" function of trial judges. In so doing, the Court will provide necessary and timely guidance to litigants and district courts, and will greatly aid the task of appellate review.

SUMMARY OF ARGUMENT

> Trial judges must exercise sound discretion as gatekeepers of expert testimony under *Daubert*. [Defendant], however, would elevate them to the role of St. Peter at the gates of heaven, performing a searching inquiry into the depth of an expert witnesses's soul — separating the saved from the damned. Such an inquiry would inexorably lead to evaluating witness credibility and weight of the evidence, the ageless role of the jury.

McCullock v. H.B. Fuller Company, 61 F.3d 1038, 1045 (2nd Cir. 1995).

In *Daubert v. Merrell Dow Pharmaceuticals*, this Court held that the Federal Rules of Evidence "relaxed" the traditional standard for the admissibility of expert scientific testimony and established a limited gatekeeping role for district courts pursuant to which trial judges should determine only whether proffered

scientific testimony is "reliable" and "relevant." The Court held that scientific testimony is reliable if the expert's "methodology" is sound. The Court stressed that the methodology inquiry is a "flexible one," which should not include an assessment of the correctness of the expert's conclusions. The Court further held that expert scientific testimony is relevant if it will assist the trier of fact to understand the evidence or to determine a fact in issue. Finally, the Court stressed the distinction between the admissibility and the "sufficiency" of scientific testimony, pointing out that the jury system is the appropriate forum for addressing challenges to the sufficiency of such testimony through cross examination, presentation of contrary evidence, and careful jury instructions.

Contrary to the arguments of Petitioners and their *amici*, the United States Court of Appeals for the Eleventh Circuit properly interpreted and applied the Federal Rules and *Daubert*. The Eleventh Circuit carefully followed this Court's instruction that the Federal Rules provide the framework for determining the admissibility of expert testimony; that under the "liberal thrust" of the Federal Rules, traditional barriers to opinion testimony have been "relaxed"; that to be admissible, expert scientific testimony must only be "reliable" and "relevant"; that expert scientific testimony is reliable if the expert's "methodology" is sound; that the methodology inquiry is a "flexible one," which must focus on the expert's reasoning and not upon his conclusions; that expert scientific testimony is relevant if it will assist the jury in determining facts in dispute; and, that the trial judge's gatekeeping responsibility does not extend to assessing the sufficiency of a litigant's evidence or rendering scientific opinions.

Petitioners and their *amici* ignore *Daubert*'s teachings. Disregarding what *Daubert* actually said, they seek to turn the case on its head and create a heightened standard for the

admissibility of expert scientific testimony that would essentially require judges to act as jurors and "amateur scientists." Petitioners and their *amici* act as if the Court in *Daubert* rejected the liberal thrust of the Federal Rules of Evidence and imposed new "formidable burdens" on the proponents of expert testimony, requiring that judges subject such testimony to "more penetrating pretrial scrutiny." *Daubert*, however, did nothing of the sort.

Petitioners and their *amici* act as if *Daubert* held that the admissibility of a scientist's testimony depends upon the correctness or general acceptance of his conclusions, ignoring this Court's instruction that the focus should only be on the expert's methodology. Disregard of this Court's admonition that the "focus" of the reliability assessment be "solely on principles and methodology, not on the conclusions that they generate," would impermissibly permit (if not obligate) trial judges to decide the correctness of an expert's opinions, nullify the "ageless role of the jury," and encourage jurists to act as "amateur scientists." As the Eleventh Circuit properly observed, trial judges must be "careful not to cross the line between deciding whether the expert's testimony is based on 'scientifically valid principles' and deciding the correctness of the expert's conclusions . . . the gatekeeping responsibility of the trial courts is not to weigh or choose between conflicting scientific opinions, or to analyze and study the science in question in order to reach its own scientific conclusions." *Joiner v. General Electric Co.*, 78 F.3d 524, 530 (11th Cir. 1996).

Petitioners and their *amici* act as if *Daubert* established a definitive set of factors for trial courts to use in determining whether an expert's methodology is reliable. Although this Court emphasized that the methodology inquiry is to be a "flexible one," and that many factors might bear on the analysis, Petitioners and their *amici* argue that the four factors discussed in the Court's "general observations" about what may constitute

reliable methodology — testability, publication/peer review, error rate and general acceptance — must be satisfied in order for scientific testimony to be admissible. Such an "inflexible" approach is incompatible with this Court's instruction in *Daubert*, and would prevent reliable and relevant scientific testimony from being heard by juries.

Petitioners and their *amici* also act as if *Daubert* authorized trial judges to exclude scientific testimony from evidence if they find it unpersuasive, ignoring the critical distinction between the admissibility and the sufficiency of scientific testimony. Unlike the admissibility determination, the sufficiency inquiry, which asks whether the collective weight of a litigant's evidence is adequate to present a jury question, lies further down the "litigational road." Petitioners and their *amici* would take a short cut down that road to have judges determine the merits of an expert's conclusions and the weight of the totality of a plaintiff's evidence in the context of lengthy and costly pre-jury trial bench trials on the ultimate question of causation. Such an approach is at odds with *Daubert*, and would essentially require the re-drafting of the Federal Rules.

To achieve judicial uniformity in admitting expert scientific testimony, to avoid the inappropriate exclusion of reliable and relevant testimony, and to preserve the jury-adversarial system as the means of resolving factual disputes, the Court should take this opportunity to re-emphasize the limited nature of the trial judge's gatekeeping function. Trial judges should not perform "a searching inquiry" into an expert's conclusions or "witness credibility and weight of the evidence" — rather, they should decide the admissibility of scientific expert testimony pursuant to the language and spirit of the Federal Rules and the instruction of this Court in *Daubert*.

ARGUMENT

I.

IN *DAUBERT*, THIS COURT HELD THAT THE FEDERAL RULES "RELAXED" THE TRADITIONAL STANDARD FOR THE ADMISSIBILITY OF EXPERT SCIENTIFIC TESTIMONY AND ESTABLISHED A LIMITED GATEKEEPING ROLE FOR TRIAL JUDGES.

In *Daubert*, this Court articulated a new and "relaxed" procedure for determining the admissibility of expert scientific testimony. The essential points of *Daubert* are as follows:

- Fed. R. Evid. 104(a) and 702 provide the framework for determining the admissibility of expert scientific testimony in federal courts. *Daubert*, 509 U.S. at 587-593.

- This Court rejected the defendant's argument that the "general acceptance" test articulated in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) should govern the admissibility analysis, and agreed with the plaintiff that the standard for admissibility should not be so "rigid." *Daubert*, 509 U.S. at 587-588.

- The Court concluded that the "rigid general acceptance requirement would be at odds with the liberal thrust of the Federal Rules and their general approach of relaxing the traditional barriers to 'opinion' testimony." *Daubert*, 509 U.S. at 588.

- In rejecting the general acceptance test advocated by the defendant, the Court ruled that Rule 702 requires trial judges to ensure, in their "gatekeeping role," only that the proffered scientific testimony is "reliable" and "relevant." *Daubert*, 509 U.S. at 590-591.

- The Court stated that "reliability" turns on whether the expert's "methodology" is sound. The Court emphasized that the judge's "focus, of course, must be solely on principles and methodology, not on the conclusions they generate." *Daubert*, 509 U.S. at 595.

- Although the Court offered "general observations" that could bear upon the "reliability" of scientific evidence, the Court stressed that "[m]any factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test," and "emphasized" that the inquiry is a "flexible one." *Daubert*, 509 U.S. at 593-594.

- The Court held that expert scientific testimony is "relevant," or "fits," if it relates to an issue at hand, *i.e.*, if it will "assist the trier of fact to understand the evidence or to determine a fact in issue." *Daubert*, 509 U.S. at 591.

- The Court noted the defendant's concern that adopting a more "relaxed" approach to the admission of scientific testimony would prompt "befuddled juries" to be "confounded by absurd and irrational pseudoscientific assertions," but said the defendant "seems to us to be overly pessimistic about the capabilities of the jury and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 595-96.

- The Court also noted that if the "scintilla of evidence presented" is "insufficient," a trial judge "remains free to direct judgment" or "grant summary judgment" under the standards applicable to those "conventional devices," but not to resort to "wholesale exclusion" under Rule 702. *Daubert*, 509 U.S. at 596.

II.

THE ELEVENTH CIRCUIT PROPERLY APPLIED *DAUBERT*'S TEACHINGS.

Petitioners and their *amici* argue the Eleventh Circuit misstated and misapplied the requirements of Rule 702 and *Daubert*. *See, e.g., Brief for Petitioners* at 45 (claiming the Eleventh Circuit "misunderstood the requirements of Rule 702 and misapplied *Daubert*"); *Brief Of The Dow Chemical Company* at 13 (arguing "the court of appeals endorsed an interpretation of *Daubert* and the Federal Rules of Evidence that is erroneous as a matter of law"); *Brief Of The American Medical Association* at 5, 9-10 (asserting the "criteria applied by the Eleventh Circuit are inconsistent with *Daubert*," and that the "court of appeals improperly limited the factors that may be considered by a district court in determining the admissibility of expert testimony"); *Brief Of The Chemical Manufacturers Association* at 14 (arguing the Eleventh Circuit erred in "seriously misinterpreting and misapplying *Daubert*'s core holding"). In fact, however, the Eleventh Circuit accurately defined and applied the *Daubert* admissibility test:

- Following *Daubert*, the Eleventh Circuit observed that the Federal Rules of Evidence "superseded the *Frye* general acceptance test," and that the Rules "introduced a more liberal approach to the question of admissibility of scientific evidence." *Joiner*, 78 F.3d at 529.

- Citing *Daubert*, the Eleventh Circuit stated "the critical concerns of Rule 702 are evidentiary reliability and relevancy." *Joiner*, 78 F.3d at 529.

- Following *Daubert*, the Eleventh Circuit stated that, in assessing the "reliability" of expert scientific testimony, the

"district court must examine the reasoning or methodology underlying the expert opinion," but must "be careful not to cross the line between deciding whether the expert's testimony is based on 'scientifically valid principles' and deciding upon the correctness of the expert's conclusions. The latter inquiry is for the jury. . . ." *Joiner*, 78 F.3d at 530.

- The Eleventh Circuit recounted this Court's "general observations" that could bear on the reliability inquiry and, in accord with *Daubert*'s cautionary language, held that the "factors are neither exhaustive nor applicable in every case." *Joiner*, 78 F.3d at 530.

- Consistent with *Daubert*, the Eleventh Circuit explained that the "relevance" or "fit" requirement is determined by "whether expert testimony offered in the case in sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Joiner*, 78 F.3d at 530.

- In light of *Daubert*'s emphasis upon the jury trial as the appropriate forum for determining the sufficiency of an expert's testimony, the Eleventh Circuit stated that in "analyzing the admissibility of expert testimony, it is important for trial courts to keep in mind the separate functions of judge and jury," and stressed that "the gatekeeping role" is "not intended to turn judges into jurors" or to require them to "weigh or choose between conflicting scientific opinions." *Joiner*, 78 F.3d at 530.

- Consistent with Chief Justice Rehnquist's observation, in his partial dissent in *Daubert*, that the Federal Rules do not impose on trial judges "the obligation or the authority to become amateur scientists," the Eleventh Circuit warned that the "gatekeeping role" is "not intended to turn judges into . . . surrogate scientists" or to require them to "analyze or study the science in question in order to reach [their] own scientific conclusions from the material in the field." *Joiner*, 78 F.3d at 530.

III.

PETITIONERS AND THEIR *AMICI* ARE ATTEMPTING TO TURN *DAUBERT* ON ITS HEAD AND CREATE A HEIGHTENED STANDARD FOR THE ADMISSIBILITY OF SCIENTIFIC TESTIMONY THAT WOULD REQUIRE TRIAL JUDGES TO ACT AS JURORS AND AMATEUR SCIENTISTS.

Although the question before the Court is the appropriate standard of appellate review of district court decisions excluding expert scientific testimony under *Daubert*, Petitioners and their *amici* argue extensively — and, as we have shown, incorrectly — that the Eleventh Circuit misread and misapplied *Daubert*'s teachings. In so doing, they attempt to turn *Daubert* on its head, offering a skewed interpretation of the case that would, if adopted, create a heightened standard for the admissibility of expert scientific testimony that would require trial judges to assume the roles of jurors and "amateur scientists." Indeed, Petitioners and their *amici* act as if Rule 702 and *Daubert*: (a) raised the standard for admissibility of expert scientific testimony; (b) directed that the admissibility determination depends upon the conclusions of the expert; (c) established a rigid and definitive checklist for determining whether expert testimony is reliable; and (d) authorized trial judges to exclude scientific testimony from evidence if they find it unpersuasive.

A. Petitioners And Their *Amici* Wrongly Act As If *Daubert* Rejected The Federal Rules Of Evidence.

Although this Court unequivocally rejected the rigid "general acceptance" test in *Daubert* and adopted, consistent with the liberal thrust of the Federal Rules, a more "relaxed" approach to deciding the admissibility of expert scientific testimony, Petitioners and their *amici* ignore these principles

and assert that *Daubert* imposed "formidable burdens" on the proponents of such testimony, and "clearly requires that judges subject expert evidence to more penetrating pretrial scrutiny." *See, e.g., Brief Of The Dow Chemical Company* at 13 (arguing "*Daubert* imposes formidable burdens on experts to demonstrate the reliability and relevance of their theories to the satisfaction of the district court"); *Brief Of The American Medical Association* at 10 (asserting that "contrary" to endorsing a more "liberal" or "permissive" approach to the admissibility of expert scientific testimony, "*Daubert* clearly requires trial judges to subject expert evidence to more penetrating pretrial scrutiny"); *Brief Of The Pharmaceutical Research And Manufacturers Of America* at 9, 21 (claiming *Daubert* requires that "a trial court must scrutinize each aspect of the methodology that an expert uses to reach a conclusion" as part of the "complex inquiry that district courts must conduct under Rule 702"); *Brief Of The Chamber Of Commerce Of The United States Of America* at 27 (arguing the "core of *Daubert* is its requirement for an intensive analysis of both the methodology and reasoning underlying the expert's opinion").

There is no support in Rule 702 or *Daubert* for these statements of a heightened admissibility test. *See Daubert*, 509 U.S. at 587-88. Similarly, most circuit courts have followed *Daubert* in observing that a stringent admissibility test is inconsistent with the "permissive backdrop" of the Federal Rules of Evidence.[2]

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2. *See, e.g., Joiner*, 78 F.3d at 529-530; *Borawick v. Shay*, 68 F.3d 597, 610 (2nd Cir. 1996) ("by loosening the strictures on scientific evidence set by *Frye*, *Daubert* reinforces the idea that there should be a presumption of admissibility of evidence"); *McCullock*, 61 F.3d at 1042 ("*Frye's* rigid standard was inconsistent with the liberal thrust of the federal rules"); *In Re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717, 741 (3rd Cir. 1994) (noted *Daubert*'s rejection of the *Frye* test and its endorsement of "Rule 702's liberal policy of admissibility"), *cert. denied*, 115 S. Ct. 1253 (1995); *United States v. Jones*, 107 F.3d 1147, 1156 (6th Cir. 1997) (observing *Daubert*'s rejection (Cont'd)

B. Petitioners And Their *Amici* Wrongly Act As If *Daubert* Held That Admissibility Depends Upon The Expert's Conclusions.

In arguing that the Eleventh Circuit misinterpreted *Daubert*, several of Petitioners' *amici* blatantly disregard the bright line this Court drew between a scientist's methodology — which *should* be considered in determining admissibility — and his conclusions — which *should not* be considered. They incorrectly assert that the methodology-conclusion distinction is "artificial" and has been rejected by "most courts." *See, e.g., Brief Of The New England Journal Of Medicine* at 16 (arguing that "any distinction between methodology and conclusions is artificial"); *Brief Of The Dow Chemical Company* at 16-17 (citing two cases for the proposition that "most cases applying *Daubert* have agreed that the distinction between methodology and conclusions upon which the Eleventh Circuit relied so heavily has only limited practical import"); *Brief For The United States* at 26 (asserting *Daubert* "mandated" that trial judges determine the "analytical gap" between an expert's "conclusions and the scientific materials on which they purportedly relied"); *Brief Of Chemical Manufacturers Association* at 15, 17 (stating that under Rule 702 a court may focus on methodology and the

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of the "general acceptance" standard and noting the "relaxed standard in Rule 702 governing expert scientific testimony"); *United States v. Davis*, 40 F.3d 1069, 1073, n.4 (10th Cir. 1994) (noting that *Daubert* "has replaced the historical *Frye*" standard, and observing that the new standard adopts the "liberal thrust" of the Federal Rules); *Ambrosini v. Labarraque*, 101 F.3d 129, 133 (D.C. Cir. 1996) (noting *Daubert*'s rejection of the "rigid" *Frye* test, and adoption of an approach consistent with the "liberal thrust" of the Federal Rules). *See also*, Cranor, *Judicial Boundary Drawing And The Need For Context-Sensitive Science in Toxic Torts After Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 16 Va. Environ. L.J. at 1, 13 (Fall 1996) ("In *Daubert*, the Supreme Court appears to have rendered an opinion liberalizing the standard for the admissibility of scientific evidence").

"conclusions themselves"). *Amici*'s arguments are contrary to the admonition by this Court — and the holdings of most circuit courts — that the "focus" of the reliability assessment be "solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 596.[3]

The trial judge's assessment of an expert's methodology should be no more complex than asking whether the way in which the expert went about reaching his conclusion — his

3. The majority of circuit courts have followed this Court's instruction that the reliability inquiry entails an examination only of the soundness of the methodology employed by the proposed expert, not of the expert's conclusions. *See, e.g., Joiner*, 78 F.3d at 530; *In re Joint Eastern and Southern District Asbestos Litigation*, 52 F.3d 1124, 1132 (2nd Cir. 1995) (emphasizing that the trial judge must not "cross the line" between evaluating an expert's methodology and the strength of his conclusions); *In re Paoli*, 35 F.3d at 744 (the analytical focus "must be solely on principles and methodology"); *Smelser v. Norfolk Southern Railway Company*, 105 F.3d 299, 303 (6th Cir. 1997) ("when considering reliability, the trial court must focus on the soundness of the expert's methodology and not the correctness of his conclusions"); *Cummins v. Lyle Industries*, 93 F.3d 362, 368 (7th Cir. 1996) ("the focus must be solely on principles and methodology, not the conclusions they generate"); *Hopkins v. Dow Corning Corporation*, 33 F.3d 1116, 1124 (9th Cir. 1994) (the "inquiry must be solely on principles and methodology"), *cert. denied*, 115 S. Ct. 734 (1995); *Compton v. Subaru of America, Inc.*, 82 F.3d 1513, 1518 (10th Cir. 1996) (the focus "must be solely on principles and methodology"); *Ambrosini*, 101 F.3d at 134 ("Under the first prong of the analysis, the district court's focus is on the methodology or reasoning employed"). *See also*, Mills, *Daubert v. Merrell Dow Pharmaceuticals, Inc., On Remand: The Ninth Circuit Loses Its Way In The 'Brave New World'*, 26 Ga. L. Rev. at 849, 874-75 (1995) ("Nowhere does the [*Daubert*] court imply that lower courts should even consider the substance of the expert's conclusion when determining admissibility under Rule 702"); Chesebro, *Taking Daubert's Focus Seriously: The Methodology/Conclusion Distinction*, 15 Cardozo L. Rev. at 1747, 1748 (1994) ("It is completely inappropriate . . . to advance Rule 702 admissibility arguments that depend upon the ultimate conclusion reached by the expert").

reasoning, his analytical approach — is grounded in sound scientific principles. Neither Rule 702 nor *Daubert* permit a trial judge to exclude expert testimony simply because the expert's opinion — or even his approach — is not "generally accepted."[4] Moreover, as long as the methodology employed by the expert is scientifically valid, claims that the expert made errors in applying the methodology and thereby reached the wrong conclusion simply go to the weight of the testimony. As Judge Becker observed in *In re Paoli*: "[T]he judge should not exclude evidence simply because he or she thinks there is a flaw in the expert's investigative process which renders the expert's conclusions incorrect." 35 F.3d at 746.

In *Daubert*, this Court drew a sharp distinction between methodology and conclusion recognizing that an admissibility rule that permits or directs trial judges to determine the flaws in or the correctness of an expert's conclusions would unavoidably intrude upon the "ageless role of the jury." *McCullock*, 61 F.3d at 1045. When a court rejects scientific testimony on the grounds that an expert's methodology is inconsistent with the conclusions of most other experts, or because the judge perceives that the "analytical gap" between the expert's reasoning and his conclusions is "too wide," the judge is rendering a decision based

4. *See, e.g., McCullock*, 61 F.3d at 1042 ("*Daubert* granted the trial judge the discretion and authority to determine whether scientific evidence is trustworthy, even if the technique involved had not yet won general scientific acclaim"); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1319, n.11 (9th Cir. 1995) ("The focus under *Daubert* is on the reliability of the methodology, and in addressing that question the court and the parties are not limited to what is generally accepted; methods accepted by a minority in the scientific community may well be sufficient"), *cert. denied*, 116 S. Ct. 189 (1995); *Braun v. Lorillard, Inc.*, 84 F.3d 230, 234 (7th Cir. 1996) ("The opinion evidence of reputable scientists is admissible in evidence in a federal trial even if the particular methods they used in arriving at their opinion are not yet accepted as canonical in their branch of the scientific community") *cert. denied*, 117 S. Ct. 480 (1996).

on his perceived strength of the testimony. While consideration of the strength of the proffered testimony may be appropriate in the context of deciding motions for summary judgment or directed verdict, such an assessment of the evidence is not proper in the context of ruling on admissibility. As the Eleventh Circuit properly observed, the "gatekeeping" role is "not intended to turn judges into jurors" or to require them to "weigh or choose between conflicting scientific opinions." *Joiner*, 78 F.3d at 530.

Allowing trial judges to determine the accuracy of an expert's scientific conclusions would have the additional and unfortunate consequence of turning judges into "amateur" or "surrogate" scientists. *Daubert*, 509 U.S. at 600 (partial dissent by Chief Justice Rehnquist); *Joiner*, 78 F.3d at 530. The courtroom is, of course, not a laboratory, and judges are neither trained nor authorized to make "scientific" conclusions.[5] As much as some scientific and

5. Implicit in the Federal Rules of Evidence is the distance trial judges are expected to maintain from scientific analysis and conclusions. Rule 706, for example, permits district courts to appoint neutral scientific advisors to assist the court and the jury in understanding and applying scientific information. Fed. R. Evid. 706. Several Petitioners' *amici*, including The New England Journal of Medicine and The Dow Chemical Company, recommend an increased use of Rule 706 to assist judges in rendering admissibility decisions, and point to *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996) as a model of how federal judges can effectively use court-appointed scientists to exclude expert testimony. *See Brief Of The New England Journal Of Medicine* at 2, 18-19; *Brief Of The Dow Chemical Company* at 2-3. *Hall* is, however, an abysmal example of the use of court-appointed experts in the context of a *Daubert* inquiry. The judge in *Hall* appointed "neutral" scientists to assist him in determining the admissibility of expert scientific testimony offered by plaintiffs in support of their claims that silicone-gel breast implants caused their illnesses and then excluded the testimony of all of plaintiffs' experts. In so doing, the district court inexplicably *disregarded the opinions of several of his scientific advisors* that the methodologies employed by plaintiffs' experts *were reliable*. 947 F. Supp. at 1446, 1448-51, 1470, 1472-73. Although the same or substantially similar expert testimony has been admitted in dozens of breast implant cases

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medical organizations wish to infuse all federal judges with scientists' sensibilities and priorities, it is neither feasible nor desirable. For example, *amicus* The New England Journal of Medicine states that the task of the Journal's executive editor, Marsha Angell, M.D., in deciding "what medical research studies are admitted into the scientific literature," is "analogous" to the gatekeeping role performed by trial judges in determining the admissibility of scientific evidence. *Brief Of The New England Journal Of Medicine* at 2-3. With all due respect to Dr. Angell and her colleagues, their job bears no meaningful resemblance to the responsibility of a federal trial judge in deciding whether a sick or injured plaintiff will be permitted to present his or her claims to a jury. Unlike the deliberative scientific process and the political and bureaucratic system of journal publication, the universe in which trial judges, lawyers and litigants operate involves human beings with immediate problems, statutes of limitation, unique burdens of proof, and separate roles for judges and juries. Moreover, when the New England Journal of Medicine rejects a study, the author is free to submit his work to another publication. Plaintiffs, of course, do not get a second bite of the apple. As imperfect as it may be, there is no place in the adversarial jury system for trial judges to take on the additional burden of being "amateur scientists."

C. Petitioners And Their *Amici* Wrongly Act As If *Daubert* Established A Rigid And Definitive Checklist For Deciding Whether Expert Testimony Is Reliable.

Petitioners and their *amici* also ignore *Daubert*'s direction that the district court's inquiry into the validity of a scientific

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throughout the country, the judge in *Hall* premised his ruling on his misplaced beliefs that the "interjection of the *Daubert* standards into the screening process for proposed scientific evidence has *substantially heightened the scrutiny* through which such evidence must pass," that the distinction between methodology and conclusion is "*superficial*," and that "the issue before the court . . . is *causation*." *Id.* at 1401, 1415 (emphasis added).

expert's methodology is to be a "flexible one." *Daubert*, 509 U.S. at 593-94. Instead, they argue that scientific testimony must satisfy each of the four factors mentioned in *Daubert*'s "general observations" about reliability — testability, publication/peer review, error rate and general acceptance — in order to be admissible. For example, Petitioners complain that the Eleventh Circuit erred in finding that "the extensive experience and specialized expertise of each of these experts *augment* the reliability of their reasoning and methodology," *Joiner*, 78 F.3d at 532 (emphasis added), because it considered "a factor not even listed by this Court in *Daubert*." *Brief Of Petitioners* at 46.[6] *See also, Brief Of The Pharmaceutical Research Manufacturers Of America* at 7-8 (arguing that the "four factors" described in *Daubert* "must be applied with rigor to carry out *Daubert*'s gatekeeping mandate properly.")

Far from "mandating" bright-line criteria for evaluating the reliability of expert scientific testimony, *Daubert* did "not presume to set out a definitive checklist or test." *Daubert*, 509 U.S. at 593-94. Although the Court clearly intended its "general observations" to be just that, and though most circuit courts have read the "observations" to be illustrative and not exhaustive or applicable in every factual situation[7], opponents of the admission

6. Contrary to Petitioners' suggestion that the Eleventh Circuit focused exclusively, or too greatly, on the "extensive experience and specialized expertise" of the experts, the Court of Appeals clearly considered these factors in addition to, or augmenting, its review of the experts' reasoning and methodologies. *Joiner*, 78 F.3d at 532 ("While this factor is most pertinent in deciding the separate question of whether the experts are qualified to testify, see Fed.R.Evid. 702, it also has some bearing on the determination of the reliability of the underlying reasoning or methodology").

7. Most circuit court decisions have followed *Daubert*'s direction that the methodology inquiry is to be to a "flexible one." *See, e.g., Joiner*, 78 F.3d at 530; *Borawick*, 68 F.3d at 610 (*Daubert* "emphasizes the need for flexibility
(Cont'd)

of scientific evidence, such as Petitioners and their *amici*, repeatedly urge trial courts to exclude testimony that does not comply with the "*Daubert* factors."

In his partial dissent in *Daubert*, Chief Justice Rehnquist foresaw the potential for misunderstanding and misuse of the Court's "general observations": "General observations by this Court customarily carry great weight with lower federal courts, but the ones offered here suffer from the flaw common to most such observations — they are not applied to deciding whether particular testimony was or was not admissible, therefore they tend to be not only general, but vague and abstract." *Daubert*, 509 U.S. at 598.[8] The Court should use this occasion to again "stress the flexibility" of the admissibility inquiry described in *Daubert*. Strict application of the Court's "general observations"

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in assessing whether evidence is admissible," permitting "the trial judge to weigh the various considerations pertinent to the issue in question"); *In re Paoli*, 35 F.3d at 742 ("And *Daubert*, like *Downing*, indicates that the inquiry as to whether particular scientific technique or method is reliable is a flexible one"); *Benedi v. McNeil-P.P.C.*, 66 F.3d 1378, 1383 (4th Cir. 1995) (in "offering these guidelines, the [*Daubert*] court emphasized that it was not formulating a rigid test or checklist, relying instead on the ability of the federal judges to properly determine admissibility"); *Daubert*, 43 F.3d at 1316-17 (9th Cir. 1994) (reading *Daubert*'s "general observations" as "illustrative rather than exhaustive; similarly we do not deem each of them to be equally applicable (or applicable at all) in every case"); *Ambrosini*, 101 F.3d at 133-34 (emphasizing that the methodology inquiry is a "flexible one" and that "none of the factors discussed is necessarily applicable in every case or dispositive; nor are the four factors exhaustive").

8. *See also*, Cranor, *supra* at n.2 at 14 ("The Court did stress the flexibility of the trial court examination of the question, but, in assigning the daunting task of ruling on the admissibility of extremely complicated, technical, and sometimes novel scientific techniques, it may have tempted trial judges to look at a set of fixed criteria to handle this difficult procedure").

would result in the heightened admissibility test advocated by Petitioners and their *amici* and would prevent reliable and relevant scientific evidence from being heard by juries.[9]

D. Petitioners And Their *Amici* Wrongly Act As If *Daubert* Authorized Trial Judges To Exclude Scientific Testimony From Evidence If They Find It Unpersuasive.

Finally, Petitioners and their *amici* disregard the distinction this Court drew in *Daubert* between the admissibility of evidence and its sufficiency. In so doing, they essentially act as if *Daubert* authorized trial judges to simply exclude scientific testimony from evidence if they find it unpersuasive. This Court in *Daubert* held precisely the opposite — finding the defendant "overly pessimistic about the capabilities of the jury and the adversary system generally." *Daubert*, 509 U.S. at 595-96.

9. Some of Petitioners' *amici* would further restrict the *Daubert* admissibility by limiting the kind of scientific evidence an expert may rely upon in formulating his opinions. They would restrict such evidence to epidemiological studies, and bar such other reliable scientific evidence as animal studies, *in vitro* studies, medical diagnoses and case reports. *See, e.g., Brief Of The New England Journal Of Medicine* at 9 (arguing only epidemiological studies can establish a "link between a risk factor and a disease" in the "first place"); *Brief Of The American Medical Association* at 11-15 (suggesting that disease causation can only be shown if there is determinative epidemiology); *Brief Of The Pharmaceutical Research And Manufacturers Of America* at 11 (arguing that "animal studies, without confirmation through rigorous epidemiological or evidence in humans, do not provide a sufficient basis for an expert to assert causation in humans"). There is no support in the Federal Rules or *Daubert* for such limitations on the types of evidence that an expert may rely upon to satisfy the *Daubert* test. *See, e.g., Benedi*, 66 F.3d at 1384 ("We do not read *Daubert* as restricting expert testimony to opinions that are based solely upon epidemiological data"); *In re Paoli*, 35 F.3d at 758-59 (admitting expert testimony based on differential diagnosis, and not epidemiology); *Hopkins*, 33 F.3d at 1124 (permitting experts to base their opinions on scientific data and techniques "relied upon by medical experts in making determinations regarding toxic causation where there is no solid body of epidemiological data to review").

As a practical matter, the "conclusions" of scientific witnesses (at least in toxic tort cases) typically concern, directly or indirectly, whether a particular substance can and/or did cause a disease or adverse condition in one exposed to the substance. The question of causation is, unlike the admissibility issue, a matter of the "sufficiency" of the totality of a plaintiff's evidence. *See, e.g., In re Joint Eastern and Southern District Asbestos Litigation*, 52 F.3d at 1133 ("Unlike admissibility assessments, which involve decisions about individual pieces of evidence, sufficiency assessments entail a review of the sum total of a plaintiff's evidence").

In *Asbestos Litigation*, the Second Circuit emphasized the distinction between the trial court's role in "assessing the admissibility of scientific evidence in federal court as articulated by the Supreme Court in *Daubert*," and its consideration of the "sufficiency of scientific evidence" that bears on the factual issue of causation. 52 F.3d at 1131-32. The district court entered judgment as a matter of law in favor of the defendants following the jury's verdict that the plaintiff had died of colon cancer caused by asbestos exposure. The trial court based its ruling on its independent assessment of the plaintiff's evidence and expert testimony. *Id.* at 1130. The Second Circuit reversed, holding that the "district court overstepped the boundaries set forth in *Daubert*. It impermissibly crossed the line from assessing evidentiary reliability to usurping the role of the jury." *Id.* at 1131. In so ruling, the court pointed out that:

> "[A]dmissibility" and "sufficiency" of scientific evidence necessitate different inquires and involve different stakes. Admissibility entails a threshold inquiry over whether a certain piece of evidence ought to be admitted at trial. The *Daubert* opinion was primarily about admissibility. It focused on the district court's role in evaluating the methodology and the applicability of contested scientific evidence in admissibility decisions.

Id. at 1132. In contrast, the court's "sufficiency inquiry, which asks whether the collective weight of a litigant's evidence is adequate to present a jury question, lies further down the litigational road." *Id.*[10]

This Court in *Daubert* emphasized that the reliability-relevance admissibility standard is *not* intended to replace such "traditional" devices for challenging the sufficiency of scientific evidence as cross-examination, the presentation of contrary evidence, and thoughtful instruction on the burden of proof. *Daubert*, 509 U.S. at 595-96. Petitioners and their *amici* would have trial judges assess the sufficiency of a plaintiff's scientific evidence, including the conclusions of her experts, during pre-trial admissibility hearings. Indeed, the argument of Petitioners and their *amici* boils down to the proposition that the expert

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10. *See Joiner*, 78 F.3d at 534 (Circuit Judge Birch, in a special concurrence, stated that the "sufficiency of the evidence and the weight of the evidence, however, are beyond the scope of the *Daubert* analysis" and that whether the "conclusions advanced from the stated premises in fact follow and the persuasiveness of those conclusions in the ultimate resolution of competing opinions, are questions appropriately left to the finder of fact"); *McCullock*, 61 F.3d at 1045 (the trial court should limit its admissibility inquiry to the questions of methodology and relevance, and avoid "evaluating witness credibility and weight of the evidence, the ageless role for the jury"); *Benedi*, 66 F.3d at 1383-84 (the focus of the court's inquiry is or methodology, leaving it to the jury to "assess the weight and credibility of the evidence"); *Ambrosini*, 101 F.3d at 1135-36 (an expert's testimony "does not warrant exclusion simply because it fails to establish the causal link to a specified degree of probability"). *See also*, Mills, *supra* at n.3 at 875 (Rule 702 "does not require that the testimony be sufficient to carry the plaintiff's burden of proof at trial").

testimony offered by the plaintiffs in the underlying action consists of "absurd and irrational pseudoscientific assertions" because they are based on an insufficient number of animal studies and wrong-headed conclusions by the experts. Even if that argument were correct, this Court in *Daubert* held that it is for the jury and the adversary system, not the trial judge, to make such a determination. Moreover, if the "scintilla" of evidence introduced by the plaintiffs is really insufficient, directed verdict or summary judgment may be proper, but "wholesale exclusion" under Rule 702 is not. *Daubert*, 509 U.S. at 596.

IV.

THIS COURT SHOULD RE-EMPHASIZE THAT THE FEDERAL RULES "RELAXED" THE STANDARD FOR THE ADMISSIBILITY OF EXPERT SCIENTIFIC TESTIMONY AND THAT THE TRIAL JUDGE'S GATEKEEPING ROLE IS A LIMITED ONE.

To achieve judicial uniformity in admitting scientific expert testimony, and to avoid the inappropriate exclusion of reliable and relevant testimony, the Court should re-emphasize the limited nature of the trial court's gatekeeping function articulated in *Daubert*. Despite the seemingly clear message of *Daubert*, Petitioners and their *amici* offer a distorted version of the reliability-relevancy admissibility test that would permit, if not obligate, trial judges to dispose of entire litigations in the context of what is supposed to be "a preliminary assessment" of the admissibility of scientific evidence. In effect, Petitioners and their *amici* urge adoption of a heightened standard for the admissibility of expert scientific testimony that would provide unprecedented litigation protection for manufacturers and distributors of pharmaceuticals, medical devices and toxic chemicals. Indeed, they promote a drastic revision of the Federal Rules of Evidence, the Federal Rules of Civil

Procedure, and the historical (and constitutionally mandated) relationship between judge and jury.

Moreover, as the proceedings below and numerous other district court cases illustrate, the approach suggested by Petitioners and *amici* would convert simple admissibility hearings — held either prior to trial or during trial as testimony is introduced — into elaborate and expensive bench mini-trials.[11] Neither the Federal Rules nor this Court in *Daubert* intended or foresaw that, in order for a plaintiff to present her case to a jury, she would first have prove her case to a judge through presentation of all of her scientific evidence and expert testimony. Neither the Federal Rules nor this Court in *Daubert* anticipated that trial judges would use such proceedings to render findings on the conclusions of the experts and the sufficiency of a plaintiff's evidence. Neither the Federal Rules nor this Court in *Daubert* contemplated that threshold admissibility hearings would evolve into summary judgment-like hearings during which the procedural protections typically afforded to plaintiffs in actual summary judgment proceedings are ignored.[12] Neither

11. *See, e.g., In re TMI Litig. Cases Consol. II*, 911 F. Supp. 775, 785-86 (M.D. Pa. 1996) and *In re TMI Litig. Cases Consol. II*, 922 F. Supp. 977, 1000 (M.D. Pa. 1996) (multiple *Daubert* hearings conducted over the course of twenty days, with testimony from more than two dozen experts, as well as the submission of voluminous scientific literature and documentary evidence); *Hall*, 947 F. Supp. 1393 (evidentiary hearing "spanned four intense days" during which the court heard the testimony of numerous scientists, and received into evidence the reports from court-appointed experts and voluminous literature and internal company documents); *Wade-Greaux v. Whitehall Laboratories, Inc.*, 874 F. Supp. 1441, 1448 (D. V.I. 1994) (the court conducted an admissibility hearing under *Daubert* "spanning seven separate days," during which testimony was "adduced from each of the plaintiffs' expert witnesses" who were "required to address both general causation and specific causation"), *aff'd*, 46 F.3d 1120 (3rd Cir. 1994).

12. In evaluating the "collective weight of a litigant's evidence" in the (Cont'd)

the Federal Rules nor this Court intended that admissibility hearings under *Daubert* would become so time-consuming and expensive — essentially requiring two trials — that sick and injured citizens would face new barriers to the courthouse. Under such a regime, individual plaintiffs could not hope to compete with the wealthy institutions and corporations on the other side.

The heightened scrutiny of proffered expert scientific testimony proposed by Petitioners and their *amici* would allow judges to substitute their judgment for a jury's in the guise of evaluating each microscopic step of a scientist's analysis. Such a process is contrary to Rule 702 and this Court's holding in *Daubert*, as well as to the constitutionally protected right to a jury trial. That being so, we respectfully submit that, whatever standard of review the Court finds applicable in this case, the Court should re-emphasize that the Federal Rules "relaxed" the standard for the admissibility of expert scientific testimony and that the trial judge's gatekeeping role is a limited one.

(Cont'd)
context of a motion for summary judgment or directed verdict, the trial judge "must view the evidence in the light most favorable to the non-movant and grant that party every reasonable inference that the jury might have drawn in its favor," and must "not assess the weight of conflicting evidence, or the credibility of the witnesses, or substitute its judgement for that of the jury." *In re Joint Eastern and Southern District Asbestos Litigation*, 52 F.3d at 1131.

CONCLUSION

The judgment of the United States Court of Appeals for the Eleventh Circuit should be affirmed.

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STATEMENT OF INTEREST OF AMICI CURIAE

Amici are physicians specializing in the field of preventive and occupational medicine (hereinafter, "occupational medicine"), as well as an international union composed of members who benefit from treatment by and consultation with those occupational medicine physicians who have devoted themselves to the understanding of the health problems affecting workers in modern society. Neither the physicians herein nor the Oil, Chemical and Atomic Workers International Union have any interest in the outcome of this lawsuit.[1] However, it is our understanding that the distinction between a trial court's review of the methodology of expert witnesses rather than an evaluation of the expert's conclusions is fundamental to this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2787 (1993), If that is so, then *amici* appear on their own behalf to alert this Court to the grave misunderstanding of the district court below relating to the methodology routinely employed by practitioners in the field of occupational medicine. If the flaws in the district court's methodological analysis are perpetuated, then *amici* fear that the rights of injured workers to gain proper redress will be unduly sacrificed. We believe that we are uniquely qualified to advise this Court on the proper methodology to be followed by occupational medicine professionals, because that is the field of our professional training. Lastly, before we endeavor to request that this court affirm the decision of the court of appeals or suggest where the district court erred in its understanding of the methodology utilized by occupational medicine professionals, we must confess that we are unqualified to offer this Court guidance concerning the intricacies of the legal issues presented

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[1] More complete descriptions of *amici* are set forth in the appendix bound with this brief. Counsel for all parties have consented to the filing of this brief. Letters of consent are being filed with the Clerk. No counsel for any party authored any part of this brief, and no person other than *amici curiae*, its members as applicable, or their counsel made any monetary contribution to the preparation or submission of this brief.

by the petition for *certiorari* filed in this case.

SUMMARY OF ARGUMENT

In undertaking its duties pursuant to *Daubert* the district court misconstrued its role by attempting to evaluate the conclusions of Plaintiffs' experts rather than the methodology that they used. Not only did the district court fail to confine its role to evaluating the methodology used by Plaintiff's experts, but it also failed to understand the diagnostic methodology employed by occupational medicine professionals.

Occupational medicine is a distinct medical discipline which routinely requires practicing professionals to make judgments relating to conditions caused by chemical, occupational, and environmental exposures. The methodology used in making these judgments is differential diagnosis, which in the occupational medicine setting includes a clinical assessment, a toxicological assessment, an evaluation of all contributing factors, and then an assessment of the biological plausibility of any proposed explanation. In this effort to understand whether any hypothesized causative factor is biologically plausible, an occupational medicine professional may seek guidance from colleagues, *in vitro* studies, biophysical data, general scientific knowledge and experience, case reports, and case conferences, as well as research toxicology and epidemiology. None of these factors are exclusive and all are appropriately weighed within the overall matrix of understanding the proposed relationship.

The appropriate question for the district court below to have asked was: "Have Plaintiffs' experts used the proper methodology of their discipline to assess whether it is biologically plausible that Mr. Joiner's exposure to a carcinogenic mixture of dielectric fluids during the course of his occupation contributed in some way to his early manifestation of lung cancer at 37, even though the lung cancer was likely initiated by tobacco products?" Based upon the record before the district court, the answer would have had to have been in the affirmative. Whether it is "probable" is for the trier of fact to decide after full cross-examination and trial..

ARGUMENT

A. Basic facts relating to PCBs and the City of Thomasville

Pertinent to our understanding is a brief background of the facts as we understand them to be presented before the courts below. As stated by the district court, (36a), Appellant Monsanto manufactured polychlorinated biphenyls (PCBs) from approximately 1935 to 1977. Indeed, after 1945 Monsanto was the only manufacturer of PCBs in the United States. Appellants General Electric Company ("GE") and Westinghouse Electric Corporation ("Westinghouse") manufactured both electrical transformers and fire-resistant fluid. From the 1930s to the 1970s, both GE and Westinghouse marketed fire-resistant dielectrical fluid containing PCBs. GE's product carried the trade name "Pyranol," while Westinghouse's carried the trade name "Inerteen."

Throughout the time of Plaintiff Robert Joiner's employment all of the transformers which the City of Thomasville purchased from Defendants GE and Westinghouse used mineral oil-based dielectric fluid which was intended to be free of PCBs. However, beginning in 1983, the City of Thomasville discovered, via systematic testing, that the dielectric fluid in some of its transformers was contaminated with PCBs. From 1983 to 1993, the City tested approximately 2,668 of its transformers and determined that approximately half of the transformers tested showed PCB contamination.[2] Of these, about 2.5% contained very toxic levels of PCBs, i.e. above 500 parts per million ("ppm"), and about 16.7% contained hazardous levels above 50 ppm.[3] The district court then concluded that

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[2] According to the record below, there was also sufficient evidence for a jury to decide that dielectrical fluid in the transformers contained PCDFs and PCDDs. On the basis of the fact that issues related to these chemicals will likely be remanded to the trial court, their toxicology and carcinogenicity will not be discussed here.

[3] The Administrator of the Environmental Protection Agency has determined that any substance containing concentrations of PCBs of 50 parts per million (ppm) or greater represents an unreasonable risk of injury to health within the United States. 40 C.F.R. Section 761.20 (1996).

"almost one out of every five (i.e., 19.2%) of the transformers the City tested presented a PCB hazard." (36a-37a)

The District Court also understood that, "with limited exceptions, Congress banned the production and sale of PCBs on January 1, 1978. 15 U.S.C. Section 2605(e)(2)(A). Congress took this action because in its view PCBs 'present an unreasonable risk of injury to health of the environment.' *See* 15 U.S.C. Section 2605(a)." This Court itself has noted that oil containing PCBs is a potent carcinogen. *Midlantic Nat'l Bank v. N.J. Dept. of Envtl.Prot.*, 474 U.S. 494, 497, (1986).[4]

Indeed, despite numerous decisions by Federal courts throughout the United States that PCBs are toxic and carcinogenic substances, the district court herein held that Plaintiffs "failed to show by a preponderance of proof that their experts' opinions regarding the PCB/lung cancer link are admissible under the standards set out in Rule 702 and explicated in *Daubert* at 68A." In coming to this drastic decision that Mr. Joiner should not be allowed to have a jury of his peers decide whether his toxic exposure contributed to his lung cancer, the district court, as will be shown, both utterly misconstrued the requirements of *Daubert* as well as the

[4] This Court's view of the highly toxic nature of PCBs is in accord with that determined by other circuit and Federal courts. *In Re Paoli R.R. Yard PCB Litig.* 35 F. 3d 717, 780 (3d Cir. 1994), cert. denied, 115 S. Ct. 1253 (1995) (noting "EPA thinks that PCBs have the same carcinogenic potency as vinyl chloride, which is one of only 14 chemicals that EPA has indicated have been proven to be carcinogenic by epidemiological studies"); *Dickerson, Inc., v. U.S.*, 875 F.2d 1577, 1583 (11th Cir. 1989) (recognizing the well-documented human health and environmental hazard of PCB exposure); *Potomac Elec. Power Co. v. Sachs*, 802 F.2d 1527, 1529 (4th Cir. 1986) (holding that PCBS are highly toxic materials); *Yaffe Iron & Metal Co., Inc. v. U S E.P.A.*, 774 F.2d 1008, 1010 n.1 (10th Cir. 1985) (holding that PCBs are extremely toxic to humans and wildlife, and pose carcinogenic and other risks to humans); *In the matter of Quanta Resources Corp.*, 739 F.2d 912, 913 n.1 (3d Cir. 1984) (finding that PCBs are extremely hazardous chemicals and are themselves toxic); *Environmental Defense Fund, Inc. v. Environmental Protection Agency*, 636 F.2d 1267, 1270-71 (D.C. Cir. 1980) (holding that PCBs are extremely toxic to humans and wildlife).

methodology commonly utilized by occupational medicine professionals in making such assessments.

B. This Court's holding in *Daubert* and the standards for the testimony of experts

In June 1992, this Court in *Daubert* rejected the *Frye* "general acceptance" test for scientific evidence, *(id.* at 2792-94), and went on to make "some general observations" about proper admissibility analysis under Fed. R. Evid. 702. (*Id.* at 2796). In winding up its analysis, this Court explicitly addressed the narrow focus of Rule 702's scrutiny:

> The inquiry envisioned by Rule 702 is, we emphasize, a flexible one. Its overarching subject is the scientific validity – and thus the evidentiary relevance and reliability – of the principles that underlie a proposed submission. The focus, of course, must be solely on the principles and methodology, not on the conclusions that they generate. *(Id.* at 2797) (footnote omitted).

As such, this Court separated the focus of Rule 702 on the distinction between the "principles and methodology" used by an expert, on the one hand, and the "conclusions" thereby reached by the expert. *(Id.* at 2797).[5] Amici believe that this Court correctly understood that capable scientists may analyze the same body of data and reasonably arrive at diametrically opposed conclusions.[6] However, this is not how the district

[5] In the case of *Daubert*, Respondent (at 5) argued that the conclusion of plaintiffs' experts contradicts a "massive body of uniform scientific research" and (at 11) asserted the existence of an "overwhelming body of data that contradict their conclusion." This Court explicitly ignored Respondent's extensive factual arguments relating to the conclusions of plaintiffs' experts,treating them as irrelevant under Rule 702.

[6] As scientists, we understand that it may be disquieting to non-scientists to see scientists on opposing sides disagreeing so markedly. This cuts against an implicit assumption that disagreement among scientists should be rare, because science is capable of objective, if not always experimental, verification. In fact, though, differences of opinion are quite common in science, but the arguments are spread out over many research papers and long time spans, and they are usually couched in

court understood its function. As stated by the court of appeals: "[i]nstead of viewing the bases of an expert's opinion as a whole to screen out mere speculation, the district court assessed only a portion of the studies relied upon by each of the Joiners' experts, and then excluded the testimony because it drew different conclusions from the research than did each of the experts." Indeed, the district court even states that it was persuaded by the Defendants' attack on "the conclusions that Plaintiffs' experts draw from the studies they cite." (67a) In evaluating these conclusions, the district court failed to understand that its role was to look at methodology and completely ignored the fact that this Court has dictated that the decision to allow such testimony should weigh broadly in favor of the proponent of the evidence, consistent with the liberal thrust of the Federal Rules of Evidence. *Daubert* at 2794.

As this brief will demonstrate, one of the fundamental problems in the district court's analysis is that it failed to determine exactly what the appropriate methodology is for experts in the field of occupational medicine, assuming instead that there is a scientifically fixed methodology to which all experts must subscribe. This is not the case. An epidemiologist engaged in the practice of observing large populations often will not make or does not feel capable of making judgments on

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careful, if not polite, language. The underlying disagreements thus exist outside the courtroom as well as inside. It is only because, in a courtroom, time and space are compressed, and the nuances of language are erased in the adversary process that the disagreements appear so stark. (See *Hall v. Baxter Healthcare Corp.* 947 F. Supp. 1387, 1450 (D. 1996) where an independently appointed epidemiologist commissioned to evaluate the admissibility of the opinions of the plaintiffs' epidemiologist, Dr. Goldsmith, and the defendant's epidemiologist, Dr. Ory, concluded: "I believe there is sufficient scientific data upon which to base the opinions of both Dr. Goldsmith and Dr. Ory, the principal epidemiology witnesses, and I believe it would be appropriate to accept both of their testimonies. ... And *it is even possible for reasonable epidemiologists to arrive at diametrically opposed conclusions*, as do Drs. Ory and Dr. Goldsmith, with regards to the Hennekens study ...") (Empasis added)

individual issues of causation. If such decisions are made, it is only through the process of inductive or deductive reasoning. The experimental toxicologist who conducts research on animals may not feel competent to extrapolate the results of animal testing "directly" to humans, and, if obliged to do so, may likely describe the medical condition at issue as being "consistent with" findings in animals. However, what the district court failed to appreciate is that there is a recognized field of medical practice whose members are physicians with special knowledge and training regarding the relationship between the sickness and injuries of individual patients and conditions of work, including the physical, chemical and psychological hazards of occupation. In this discipline, practicing professionals routinely make judgments on a regular basis relating to health concerns caused by chemical, occupational, and environmental exposure. In evaluating its assignment under *Daubert*, it is the methodology used in this field and the qualifications of its pracitioners that the district court properly should have evaluated. *Amici* submit that Plaintiff's experts are qualified practitioners in the field of occupational medicine and that they reasonably employed the appropriate methodology of their discipline in forming the opinions they had regarding the etiology of the onset of Mr. Joiner's lung cancer.

C. The qualifications of plaintiffs' experts

The Joiners' chief experts were Daniel T. Teitelbaum, M.D., and Arnold Schecter, M.D., M.P.H., both of whom are practitioners in the fields of preventive and occupational medicine and clinical toxicology. According to F.R.E. 702, the first requirement of an expert witness is that the witness must have sufficient capacity in his or her field by skill, experience, training, or education.

Dr. Schecter has substantial experience in the field of PCBs, PCDFs, and PCDDs, "having devoted the last ten years of [his] life to the study of dioxins, dibenzofurans and PCBs." (Affidavit of Arnold Schecter at 7:#18.H). He is a tenured full professor of medicine at SUNY Binghamton, having previously served on the faculty at the New Jersey Medical School, SUNY

Downstate Medical School and Harvard Medical School. At the time of his testimony, he had already published over 100 papers relating to dioxins, dibenzofurans and/or PCBs, many of which had been subjected to peer review, and were cited both by other researchers and the World Health Organization. In addition, Schecter served as a peer reviewer for the ATSDR for their Toxicological Profile documents on (a) PCBs, (b) dibenzofurans, and (c) dioxins. As director of the Broome County (New York) Health Department, he saw first-hand the public health consequences of PCBs, dibenzofurans and dioxins when he evaluated exposed residents after a major fire. He spends about ten percent of his current time seeing patients. (Dep. at 143:15; Schecter Aff. at 2:#5, 2-3:#6, 5:#14.) He has advised electric companies on PCB problems they have had (Aff. at 12) and done research on these chemicals in Vietnam, Russia, China, Cambodia, and the United States. (Dep. at 147:3-11)

According to the record, Plaintiffs' other medical expert, Dr. Teitelbaum is a practicing medical toxicologist and occupational medicine specialist in Denver, Colorado. He has been an adjunct professor of Environmental Science and Engineering Ecology at the Colorado School of Mines, teaching graduate toxicology courses in occupational and environmental toxicology. He also has been an associate clinical professor of medicine at the University of Colorado Health Sciences Center. He was a founder and former director of the Rocky Mountain Poison Control Center, and of the Physicians Poison Consultation Service at the University of Colorado Medical Center. He was a founder of the American Academy of Clinical Toxicology and the American Board of Medical Toxicology, serving as the first chairman of the examining board of the American Board of Medical Toxicology.[7] Significantly, during the course of his clinical practice he has had substantial clinical experience in evaluating workers exposed to PCBs, having

[7] Dr. Teitelbaum also taught two courses on the issues of toxicology and the epidemiology of toxic diseases at the Federal Judicial Center. (Aff. at 2)

interviewed, examined, and treated numerous patients who were employed in the electrical trades. (Aff. at 3)

According to the courts below, there was no question that both Drs. Schecter and Teitelbaum were qualified to testify as practitioners in the fields of preventive and occupational medicine.[8] Indeed, given their vast experience in the area of PCBs it might even be argued that the threshold for the admissibility of their opinions should be lowered. *(See In re Paoli Railroad Yard Litigation*, at 742, noting that one factor to be considered in evaluating the admissibility of expert scientific

[8] Defendants employed three experts who were well qualified in their individual disciplines, but none of these disciplines included preventive and occupational medicine or clinical toxicology, nor did their applicable experience include more than reviewing the literature of other scientists regarding the chemicals of concern in this litigation. William J. Waddell, M.D., an experimental toxicologist at the University of Louisville Medical School, while having testified in several cases regarding PCBs (Deposition at 25:10-13), ended his clinical practice at the end of his residency (*id.* at 28:9-19), is not licensed to practice medicine in Kentucky (*Id* at 29:7-9), had no training in occupational medicine or public health (*id.* at 33: 16-19), and has never written on PCBs, PCDFs, or PCDDs (*id.* at 54: 3-5). Defendants' second expert, Philip Cole, M.D., Dr. P.H., an epidemiologist, who, according to Petitioner, testified that "he knew of no scientist who believed that [PCBs cause small cell lung cancer]," J.A. 234-35," has also testified on several occasions regarding the health effects of PCBs (Deposition 25: 9-12), but has not practiced clinical medicine since 1974 (*id.* at 31: 20-26) and did not recall ever writing anything about PCBs, PCDFs, or PCDDs. (*id.* at 35: 10-16). Lastly, William Charles Bailey, M.D., of the University of Alabama Medical School, a clinical pulmonary specialist with a sub-specialty in asthma but not in occupational medicine or clinical toxicology, was not aware of ever treating a patient who had a PCB exposure (Deposition at 17: 18-22), did not know what Inerteen (Id. 24: 25-26) or Pyranol (Id. 25: 1-5) even was, and had never written anything on PCBs or done any hands-on research in the field (25: 12-16). This is not to argue that these experts are not qualified to testify but rather that a jury should properly be given the opportunity to evaluate their testimony in light of their applicable experience and that the court should understand that the methodology utilized by their disciplines may be different from the methodology appropriately utilized by occupational medicine professionals.

testimony is "the degree to which the expert testifying is qualified.") Moreover, what the district court failed to understand is that the discipline of occupational medicine employs its own well-recognized methodology and this methodology was the one used by both Drs. Schecter and Teitelbaum. The requirements of this methodology are mandated by the understanding of clinical practice. While epidemiologists and experimental toxicologists are not required to make individual judgments of causation and may even be subject to criticism if they do so, practitioners of occupational medicine must make such judgments on a regular basis and are criticized by their patients and peers if they don't or can't.

D. The methodology of differential diagnosis

The scientifically valid methodology employed by both Drs. Schecter and Teitelbaum is that of differential diagnosis. As will be delineated, each doctor reviewed Mr. Joiner's medical history, examined the records regarding his illness, personally interviewed or conducted a physical examination of Mr. Joiner, reviewed all information regarding putative agents which may be implicated in the etiology of his condition, and then, in light of the totality of the information known or acquired, employed the usual methodology of occupational medicine physicians in trying to determine the cause of their patients' injuries. Indeed, The Federal Judicial Center's *Reference Manual on Scientific Evidence* at 214 (West 1994) defines differential diagnosis as follows:

> The method by which a physician determines what disease process has caused a patient's symptoms. The physician considers all relevant potential causes of the symptoms and then eliminates alternative causes based on a physical examination, clinical tests, and a thorough case history.

Harrison's Principles of Internal Medicine (8th edition, 1977) expresses it this way:

> The clinical method always proceeds in a series of logical steps. The perceptive student will note certain similarities between the clinical method and the scientific method. Each begins with observational data which suggest a series of

> hypotheses. The latter are tested in the light of further observations, some of which are made in the clinic and others in the laboratory. Finally, a conclusion is reached, which in science is called a *theory* and in medicine a *working diagnosis*.

It is thus clear that "differential diagnosis is a well-recognized, reliable method of medical diagnosis that has gained" widespread acceptance in the medical community and "... it is a method that involves assessing causation with respect to a particular individual." *In re Paoli R.R. Yard PCB Litigation*, at 758. Indeed, if one of the aims of *Daubert* was to ensure that experts use the same methodologies inside the courtroom as they use in their professional capacities outside of the courtroom, then differential diagnosis is plainly an appropriate methodology for scientific testimony if not the required methodology of practitioners of occupational medicine.

The first step taken by a physician in examining a patient and in attempting to come to a "differential" diagnosis is logically to make a clinical assessment of the patient, or as Dr. Teitelbaum described it, "a comprehensive and traditional occupational medical assessment of Mr. Joiner." (Aff. at 4). This is normally done through one or all of the following methodologies: 1) a review of the patient's chart, including, if possible, medical records from other treating physicians; 2) an interview with the patient in order to elicit a "history"; 3) a clinical examination of the patient; and 4) information from family members and co-workers regarding the patient's condition. The record is clear that both Drs. Teitelbaum and Schecter reviewed Mr. Joiner's medical records, personally conducted extensive interviews, and, in the form of depositions, gained information from family members and co-workers.[9] Dr.

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[9] Petitioners emphasize this in their brief (at 5), stating: "Dr. Schecter concededly had never examined him at all, and only once had even spoken to him, J.A. 103-05---in a lawyer's office, 'to get a feel for what kind of person he was, whether he was a person I would find believable.'"

In this recitation of the apparent facts, they neglect to cite from Dr. Schecter's affidavit where he fully describes the nature of his interview with Mr. Joiner: "A. I interviewed Robert Joiner and discussed with him

Teitelbaum carried out a comprehensive and traditional occupational medical assessment of Mr. Joiner,[10] during the course of which he ascertained "Mr. Joiner's current clinical condition in order to understand the genesis of his lung cancer." (Aff. at 5) He also took an extensive medical history.

In undertaking their clinical assessment of Mr. Joiner, both Drs. Schecter and Teitelbaum also conducted a toxicological assessment. The goal of this assessment was to evaluate all potential factors in the etiology of the disease in question. As has been stated, inquiries were made into Mr. Joiner's family history, his social history, and his occupational history. Potential factors relating to his disease were identified and information was gathered relating to the nature, extent, frequency and duration of any toxic exposures he might have had which could possibly be implicated in his cancer diagnosis. At the same time efforts were made to exclude alternative explanations. (Schecter Aff. at 6-7:#18)

E. The role played by smoking

The logical first step in evaluating any case of lung

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his general health, his medical history, his family medical history including but not limited to other victims of cancer, his exposure to potential carcinogens including but not limited to tobacco, his work history, and his specific tasks at work with special interest in his work involving transformer repair." As to physical examinations of Mr. Joiner himself, Dr. Schecter chose not to conduct an examination, "[b]ecause [Mr. Joiner] had a very thorough workup for his lung cancer and had been under intense medical care for a number of years when [he] saw him and [he] didn't want to put him through any more unnecessary hardship and [he] didn't feel the need for it." (Dep. of Schecter at 34:16-20)

[10]Petitioners in their brief before this Court (at 36) indicate that "Dr. Teitelbaum also had talked with respondent only once, also at the lawyers' office; without details he described what he did to be 'as complete an examination as one could do not working in one's own office.'" While it should not matter where the examination conducted by Dr. Teitelbaum took place, Dr. Teitelbaum's affidavit at 4 indicates that the examination took place in the offices of Northside/Internists and Endocrinologists in Atlanta, Georgia.

cancer is, and was in this instance, to make a toxicological assessment of tobacco. As stated by *amicus*, Marcia Angell, (at 6) "cigarette smoking is so strong a risk factor for lung cancer [that it must be evaluated in any case of lung cancer] even though we do not yet know exactly how it [causes lung cancer]." By way of history and review of records, Drs. Teitelbaum and Schecter discovered that Mr. Joiner had previously smoked cigarettes for approximately eight years. For the first five to six years of his smoking, he smoked less than one pack per day, and during the last two to three years, he never smoked more than one pack per day. He quit smoking on April 4, 1982. His wife, Karen, never smoked, though he was exposed to second-hand smoke from his mother and father. In a review of his life and family history, it was revealed that lung cancer killed his mother and maternal uncle, leaving him genetically predisposed to developing the disease. On the basis of this information, both Drs. Schecter[11] and Teitelbaum concluded that it was more likely than not that Mr. Joiner's lung cancer was initiated[12] by exposure to tobacco products.[13]

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[11] Petitioners in their b rief attempt to impeach Dr. Schecter by making it appear that in his deposition he admitted the connection between Mr. Joiner's smoking and his lung cancer, but that he deceived the court in his affidavit. They even note that "the Court of Appeals appeared unaware that in his deposition Dr. Schecter had conceded that... 'Mr. Joiner's lung cancer was equally linked to cigarette smoke and PCB exposure'" They accomplish this by quoting his affidavit out of context and leaving out the following statement: I believe that Robert Joiner's exposure to PCB contaminated mineral oil dielectric fluid served as a promotional effect on his lung cancer cells, probably initiated by cigarette exposure years before and caused him to contract lung cancer at the very young age of 37. (Affidavit of Dr. Schecter at 6:17)

[12] In cancer initiation, a minute change in the inheritable material of the cell (a mutation in the DNA) is reproduced each time the cell divides. If that initial alteration is such that the cell is changed from a normal to a malignant phenotype, then each of the progeny cells will also exhibit malignant behavior. After many cell divisions there may be a sufficient mass of malignant cells (a tumor) to disrupt the structure and function of the body and produce the symptoms and signs of the disease we call cancer. As stated by the district court, "The initiator can be any number of things including, but not limited to, tobacco smoke." (39a)

However, the question of causation which faces practitioners of occupational medicine rarely resolves simply. In this case in particular, some questions remained unanswered by the assumed connection between Mr. Joiner's lung cancer and tobacco. Although there definitely "was some risk of lung cancer [for Mr. Joiner] because he was a smoker ..., the likelihood of his developing lung cancer at age 37 on a statistical basis [would be] extremely small." (Aff. of Teitelbaum at 7-8; Aff. of Schecter at 6:#17) "If you compared the lung cancer rates at age 60, which are around 400 per 100,000 person years, with lung cancer rates in the 30's, which are almost too low to detect, somewhere around 10 to 15 per 100,000... it's pretty low risk, but it's there." (Aff. of Teitelbaum at 8) under these circumstances, the proper methodology for physicians specializing in occupational medicine would be to attempt to discern whether any other toxic exposure might reasonably have contributed to the early appearance of Mr. Joiner's cancer.[14]

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[13] If the putative agent of concern in this litigation were tobacco, one would guess that the *Daubert* analysis would not go any further and the differential diagnosis would have been sufficient to pass the district court's scrutiny without need to review epidemiological or toxicological data. This stems not from "general acceptance" in science but rather general acceptance of supposed "public knowledge." Though Dr. Teitelbaum himself subscribes to the belief that Mr. Joiner's lung cancer more likely than not was initiated by smoking, this opinion is based on the totality of the evidence and not statistical epidemiological analysis per se: "A remote smoking history of 8 pack years can only be considered a minimal risk factor for the causation of lung cancer. Such a history cannot be associated with any particular cell type of lung cancer. So few lung cancers at this age have been collected in the literature that no statistically meaningful analysis of histological type at age 37 is possible." (Teitelbaum Aff. at 8)

[14] Both scientifically and legally there seems to be a fundamental misunderstanding by Petitioners and many *amici* as to what Drs. Teitelbaum and Schecter were attempting to articulate. For instance, *amicus*, Marcia Angell, at 5 states:

> "Exposure to high levels of PCBs cannot be the sole cause of lung cancer, even if it plays some role, since people not so exposed also develop lung cancer. And exposure to high levels of PCBs do not invariably cause lung cancer, since most people so exposed remain healthy. Thus, the most that could be true is that PCBs *may contribute* to lung cancer -- that is, they might be a "risk factor" (something that increases the *chance* of developing a disease)." (emphasis in the original)

F. Occupational exposure of Mr. Joiner

The logical first step in the analysis of occupational exposure was for Drs. Teitelbaum and Schecter to take extensive histories from Mr. Joiner and review testimony from co-workers and family members. As Mr. Joiner's job involved a substantial amount of time working on electrical transformers, a videotape of the working conditions of Mr. Joiner in repairing electrical transformers was viewed and the results of testing done on the transformers was evaluated. (Schecter Dep. at; see e.g. 16:10, 17:14-20, 18:8, 18:1-.5, 33:4-13, 37:17-19)

Consistent with this review is the following summary of Mr. Joiner's work. (35a-37a) From the date of his being hired in 1973, Mr. Joiner was called upon to service transformers primarily when they had failed for one reason or another. The shop in which transformer repair was performed was below grade at the main offices of the electric company and had no forced ventilation, so and any vapors that were heavier than air remained in the workplace throughout the work day. When a transformer was in need of repair, Mr. Joiner would open it up,

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But, this is precisely the point and exactly what Drs. Teitelbaum and Schecter are stating. The only material issue both scientifically and legally is whether defendants' products affected Mr. Joiner's body in a way so as to contribute to that lung cancer by accelerating it or promoting it. Under Georgia law, a plaintiff is not required to show that the defendant's tortious conduct was the sole, primary, or initiating cause of any of his injuries. In causes of action requiring medical proof of causation, it is enough for the plaintiff to show, to a "reasonable degree of medical certainty," *Parrott v. Chatham County Hosp. Auth.*, 145 Ga. App. 2d 269, 270 (1978); *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 743 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986), that a defendant's tortious conduct contributed to the mix of preexisting factors that together ultimately caused or, at minimum, accelerated his injuries. It is even immaterial whether defendants' products would have caused Joiner's lung cancer *absent* an alternative exposure to tobacco or whether he would have *eventually* developed cancer anyway. Georgia law protects Mr. Joiner from any tortious conduct that would cause him to develop lung cancer sooner than he otherwise would have.

drain out the dielectric fluid, bake the transformer dry, test the transformer for proper operation, make repairs, and then refill the transformer with fresh mineral oil dielectric fluid. The process of repairing transformers required that Mr. Joiner stick his hands into the dielectric fluid to perform necessary repairs and disassembles. The next step required the separation of the core of the transformer from the tank so that it could be dried, cleaned, inspected and repaired. This step also exposed Mr. Joiner to the dielectric fluid. In order to dry the transformer, a process called baking out was followed. During the baking out process, the dielectric fluid which was contained in the transformers was heated, to the point of smoking, for several days with football field lights until the core was dry. At no time were any precautions taken to prevent inhalation, ingestion, or absorption of the dielectric fluid.

The obvious conclusion drawn by Drs. Teitelbaum and Schecter from this information was that Mr. Joiner likely ingested, absorbed, and inhaled substantial quantities of PCBs from the fifty-three percent of the City of Thomasville's transformers that were contaminated. He ingested these when they splashed onto his face, or touched his hands to his mouth in any way; he inhaled them during the bake-out process when the football field lights were used to vaporize the dielectric fluids; and he absorbed them through his unprotected skin when he reached into the transformers to disable them while the dielectric fluid was still in the tank.

From the analysis of this occupational history, Drs. Teitelbaum and Schecter came to the conclusion that Mr. Joiner had been exposed to substantial quantities of PCBs,[15] as well as

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[15]Petitioners have pointed to the fact that when Mr. Joiner's blood was finally tested for PCB contamination many years after his exposure began that he only had levels that would be considered background, i.e. that "PCBs in small amount are detectable at 'normal' or 'background' levels in most human beings and animals in North America." Pet. Brf. at 2. First, to call levels "normal" or "background" is an interesting euphemism employed by the defendants who are aware that PCBs would not exist on this planet at all nor be inside each of our bodies if they had not been intentionally manufactured and marketed by companies such as

PCDF and PCDD contaminants, during the course of his work. At the same time they were aware that there is a substantial body of literature regarding the harmful effects of these chemicals."[16] The question which they then faced is whether it was biologically plausible that Mr. Joiner's occupational exposure to PCBs had affected the disease process of his cancer.

G. Biological plausibility and coherence

At this point, the question properly raised by an occupational medicine professional is: "Was it biologically plausible that Mr. Joiner's heavy exposure to a likely carcinogenic mixture of dielectric fluids during the course of his occupation contributed in some way to the early manifestation at the age of 37 of his lung cancer?" In attempting to answer this question, the occupational medicine professional has no choice but to make a judgment -- to recognize that perfect congruence with the individual study question at hand and the limited fund of available information seldom permits one to be able to do more than extrapolate from all available evidence in

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Petitioners herein. Further, the district court (42a) relied on Dr. Schecter's expertise in analyzing these samples:

> "No study has been documented that examines subjects who have experienced weight loss associated with cancer, chemotherapy associated with cancer, and radiation therapy associated with cancer, as well as been subjected to excessive PCB, dioxin or dibenzofuran exposure. As a result, there is no control group to which Robert Joiner can be compared.... Adipose levels which are low do not mean that higher levels did not exist at earlier times. This is because PCBs are metabolized and excreted from the body over time."

In fact, Dr. Schecter stated at his deposition that what he found "remarkable about this man is after the weight loss and weight gain and severe cancer and cancer chemotherapy and radiation therapy, that his level [was] so high for him." (Dep. Dr. Schecter at 81).

[16] One form of PCDD, TCDD, has recently been classified as one of the very few recognized "human carcinogens." This was announced in a press release on February 14, 1997 by the World Health Organization's International Agency for Research on Cancer (IARC). The conclusion was based on the fact that it was found that TCDD was "increasing the overall risk of lung cancer and all cancers combined."

order to evaluate an association. In conducting this evaluation, perhaps the first requirements of that analysis is whether the association is both "biologically plausible" and "coherent."[17] As to "plausibility"[18], the question specifically raised here is whether, given all that is known about Mr. Joiner's history, may the available scientific evidence lead one to believe that it is "plausible" that an association between Mr. Joiner's early manifestation of lung cancer and PCBs might exist? The second factor to be viewed is "coherence," i.e. does the putative association between Mr. Joiner's lung cancer seriously conflict with the generally known facts of the natural history and biology of the disease of lung cancer.

In attempting to arrive at an answer to these questions, the occupational medicine specialist has many sources of

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[17] In 1965 Sir Austin Bradford Hill offered nine viewpoints which he believed might be "consider[ed] before deciding that the most likely interpretation of it is causation." These were listed as: 1) strength of the association; 2) consistency of the association; 3) specificity of the association; 4) temporality; 5) biological gradient (dose-response); 6) plausibility; 7) coherence; 8) experiment; and 9) analogy. In laying out these "nine different viewpoints," he accompanied them with the following caution: "What I do not believe -- and this has been suggested -- is that we can usefully lay down some hard-and-fast rules of evidence that *must* be obeyed before we accept cause and effect. None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*. What they can do, with greater or less strength, is to help us to make up our minds on the fundamental question -- is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect." [299] "Plausibility" and "coherence" are singled out here, because they are factors which are evaluated before the review of the specific evidence or data sets is begun. (Sir Autstin Bradford Hill, *"The Environment and Disease: Association or Causation?"* in *Proceedings of the Royal Society of Medicine*, 58:295-300 (1965)).

[18] Sir Austin Bradford Hill does, however, indicate that "This is a feature I am convinced we cannot [always] demand. What is biologically plausible depends on the biological knowledge of the day. ... In short, the association we observe may be one new to science or medicine and we must not dismiss it too light-heartedly as just too odd. As Sherlock Holmes advised Dr. Watson, 'when you have eliminated the impossible, whatever remains, however improbable, must be the truth.'" *Id.* at 298.

information to sift through. For instance, Dr. Schecter knew from his toxicological assessment that Mr. Joiner likely was exposed to PCBs through inhalation and he knew from his experience as a scientist that PCBs "tend to accumulate in lung tisue." (Aff. at 7:#18J) Other types of information which might be available to an occupantional medicine physician include, but are not limited to, discussions with colleagues, *in vitro* studies, biophysical data, general scientific knowledge and experience, case reports, and case conferences. Of course, they also include the observational work of epidemiologists and the experimental work of research toxicologists, But it must be cautioned that epidemiology and research toxicology, albeit very important, have their own limitations and should not be relied upon to the exclusion of all other evidence.

H. The use of observational human studies: epidemiology

If one were to compare differential diagnosis to a trial, one would describe clinical and toxicological assessment as direct evidence, while epidemiology (and research toxicology) would be akin to circumstantial evidence. By its very nature, epidemiology is not designed to answer questions of individual causation. As stated by *amicus*, Marcia Angell, "[e]pidemiologic studies yield information about probable risk factors in populations, not in individuals. They provide information about average risks in the average person in the population."(at 9D.) Moreover, epidemiological investigations are limited by the questions which are asked, i.e. the study protocol. Although a given study may be both well-designed and well-conducted, rarely can one expect the study question of an epidemiological investigation to be perfectly congruent with the question that is raised subsequently regarding an issue of individual causation. Indeed, even in the best of light, "[e]pidemiological studies are inherently capable of detecting only comparatively large increases in the relative risk. . . . Negative results cannot prove the absence of [risk]. . . ." *EPA Final Guidelines for Carcinogen Risk Assessment*, 51 Fed. Reg. 33992, 33995-96 (1986).

The subject of Mr. Joiner's exposure provides a perfect

example of the limitations of epidemiology in satisfactorily answering questions of individual causation. Prospectively, in order to answer this specific question an epidemiologist would prefer to have a study population of tens of thousands if not millions of workers who have been exposed to transformer dielectrical fluid and who smoke, and then to study the specific question of whether, for those who smoke and were exposed to PCBs there is a hastening in the mean date of diagnosis of small cell lung cancer (promotion) or a significant increase in the numbers of the study population ever so diagnosed (initiation). However, in the real world, time, money, and available study populations[19] do not allow such questions to be asked, much less answered, with particularity to the facts of any specific incident of individual causation.

Despite these inherent limitations the district court inappropriately viewed epidemiology as a *sine qua non* for legal probability. Thus, the district court assigned to itself the role of scientist and endeavored with minimal information to analyze the studies presented to it. The district court weighed the evidence from Monsanto's own in-house study which, according to the district court, showed a risk of lung cancer that was three times greater than expected, (64a) but then accepted the conclusion of the defendants that it should be disregarded because it was not "statistically significant."[20] The district court then accepted

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[19] The obvious weakness of epidemiology is that we cannot experiment on humans so our study populations must come as we find them. In the case of PCBs, comparable study populations are not easily located. Monsanto has been the only manufacturer of PCBs in the United States since World War II which limits the number of studies that may be performed in this country on manufacturing cohorts. Moreover, since these chemicals are now ubiquitous in our environment, having been ingested by each and every one of us, it is impossible to find an unexposed control population.

[20] As expressed by the epidemiologist Kenneth Rothman in his *amicus* brief to this Court in *Daubert, at 6.*: "The result of using significance testing as the criterion for decision making is that the focus is changed from the information presented by the observations themselves to conjecture about the role chance *could* have played in bringing about those observations." [emphasis in original]. Rothman is the author of a

that the study by Bertazzi, et. al., *Cancer Mortality of Capacitor Manufacturing Workers*, in *11 Am.J.Indus.Med.* 165 (1987), demonstrates an increase of lung cancer above expectations in PCB workers, but without even reading the study itself (63a n.27) rejected the study on the basis of Bertazzi's conclusion that although lung cancer deaths were above expectations, the risk estimate was not statistically significant and "such risk had never been suggested before" (63a) -- even though the district court knew that the risk had been suggested before by Monsanto's own in-house studies, which was apparently unknown to Bertazzi, *et. al.* The district court then discounts the study by Ronneberg, et al., *Mortality and Incidence of Cancer Among Oil Exposed Workers in a Norwegian Cable Manufacturing Company*, Part 2 Mortality and Cancer Incidence in 1953-84, in 45 *British J. Indus. Med.* 595, 601 (1988), regarding Norwegian cable workers, because the study, while definitely referring to a statistically significant increase in lung cancer among the exposed worker population, indicates that the cable workers were exposed to mineral oils but does not specifically define the nature of that exposure. (65a) The district court excluded this study knowing that PCBs were commonly found in such mineral oils (they were even found in the mineral oils of the City of Thomasville which were supposed to be free of PCBs) and that mineral oils themselves were the products sold by the Defendants to the City of Thomasville.

This is not to say that there is no merit at all to these individual criticisms directed to each such study by the defendants and the court. Indeed, the scientific method requires that all studies be critiqued. Furthermore, none of the studies were designed to answer the specific question raised by Mr. Joiner's cancer and inevitably every study may be faulted for its inability to answer such *sui generis* questions. For instance, in accepting the defendant's criticisms of the study by Ronneberg, the district court points out that the study was "confounded by

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standard text, *Modern Epidemiology* (Little-Brown, 1986), and Editor-in-Chief of the journal *Epidemiology*.

... exposure to cigarette smoke." While in a typical study it would be expected that a researcher would attempt to exclude cigarette smoking as a risk factor,[21] in the case of Mr. Joiner he would appropriately be a part of the study population of workers who both smoked and were exposed to PCBs.[22]

When it is accepted that each epidemiological study -- and even the very best studies -- will be subjected to appropriate criticism as to the appropriateness of their application to issues of individual causation, then one can understand that the real question to be raised before this Court is who the proper entity is to evaluate these studies in light of the questions raised. The district court, obviously, assigned that responsibility to itself rather than to the jury. As stated by the court of appeals: "In ruling the Joiners' expert testimony inadmissible, ... the district court... accepted defendants' criticisms of the conclusions reached in those studies, stating that "the studies simply do not support the experts' position that PCBs *more probably than not* promoted Joiner's lung cancer."[23] (at 12a, emphasis in the

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[21] The Ronneberg study does indicate that the results cannot be accounted for by excess smoking alone.

[22] As Dr. Teitelbaum stated in his Affidavit at p. 22: "A study of considerable importance to Mr. Joiner's case appeared in the British Journal of Industrial Medicine in 1988, in two parts. These papers by Ronneberg and colleagues, investigated the mortality and incidence of cancer among oil exposed workers in a Norwegian cable manufacturing company. In Part 2, the mortality and cancer incidence study between 1953-84, a statistically significant excess of deaths from lung cancer in transformer oil exposed workers was observed. Ten deaths from lung cancer were observed where 3.9 were expected. Nine of the cases of lung cancer occurred 20 or more years after first employment, where 2.7 would have been expected yielding a P value of 0.01, a highly significant result."

[23] Without explanation the district court also failed to review a number of the studies relied upon by Drs. Teitelbaum and Schecter. As is stated by the court of appeals: In addition, each doctor utilized numerous scientific studies and authorities. Although the district court apparently considered only four epidemiological studies and two animal studies, Teitelbaum referred to several additional studies which he utilized in forming his views. Among those not mentioned by the district court were

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If the assignment given by this Court to the trial court is to render its own independent opinion on each and every piece of scientific evidence, then there is not a single piece of evidence that cannot be ably and properly criticized as not providing a fit for the question of individual causation at hand. For instance, the trial court speaks of the need for proof not just of lung cancer but of small cell lung cancer. (53a) However, if evidence of small cell lung cancer is the appropriate judicial criteria, then the reliance on epidemiology will likely lead to a methodological impasse: in conducting a mortality study where data regarding cause of death is normally based upon diagnosis on death certificates, it will be difficult if not impossible to define a relationship of a putative carcinogen to small cell lung cancer in particular, as death certificates rarely define death more particularly than lung cancer. Indeed, any review of the literature to achieve a perfect fit will inevitably be reduced to the absurd. In the case of Mr. Joiner, if the fit required of epidemiological studies is that of small cell lung cancer in 37 year old men in Thomasville who smoked but were never exposed to any carcinogens other than PCBs, then one can readily see that no applicable epidemiological study could ever answer the question posed. .

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studies by researchers Gustavsson and Hogsted, findings of the International Program on Chemical Safety ("IPCS") World health Organization Criterion, and 'a whole series of [epidemiological studies] listed in [the World Health Organization] document.'

> Similarly, in addition to the studies mentioned in the district court's opinion, Schecter relied, in part, upon 'recent work such as that of Dr. George Lucier and colleagues at the National Institute of Health,' 'IARC studies, International Agency on Cancer at the World Health Organization,' studies by 'Dr. James Huff of the National Institute of Health,' the Zober and Theiss studies from Germany, and also Manz's study on European workers... In this case, the Joiners' experts discussed the studies of at least thirteen different researchers, and referred to several reports of the World Health Organization that address the question of whether PCBs cause cancer."

I. The use of animal studies

When an occupational medicine professional reviews animal studies, the search similarly is for biological plausibility, i.e. does the research toxicology aid in the overall conclusion of a plausible association. This is because, in theory, experimental studies are designed to demonstrate a biologically plausible mechanism by which injury could occur, as the existence of such an effect in other species or test systems may reasonably aid in explaining what has been observed in humans upon whom such tests cannot be performed. See E. K. Silbergeld, *The Role of Toxicology in Causation: A Scientific Perspective*, in 1 *Courts, Health Science & the Law* 374, 381 (1991).

Obviously, though, just as with epidemiology, there are limitations to the use of animal studies when it comes to evaluating issues of individual causation. For instance, unless the study is performed to replicate the particular individual human experience (and then it will be subjected to criticism for being the product of litigation), it is unlikely that existing animal studies will closely recreate all of the conditions upon which issues of individual causation rest. However, this does not mean that we should ignore the results of animal studies "since animals may differ from people in their response," as is indicated by *amicus* Marcia Angell at 8. Even Petitioners' own expert, Dr. William J. Waddell, indicates that using animals to extrapolate to humans "is accepted and is appropriate and proper." (Deposition of Waddell at 32:14-15]

As is evidenced in virtually all federal regulations dealing with toxic risk assessments, experimental data based on studies of animals are a critical element of the process of assessing the nature and extent of health risks associated with chemical and other exposures and in attempting to comprehend the relationship between exposures and certain adverse outcomes in humans.[24] In the courtroom, in the governmental regulatory process, and in science generally these studies all serve the same

[24] See, e.g., 42 Fed. Reg. 6532 (1977) (proposed and final discharge standards for PCBs based on animal carcinogenicity)..

purpose. They do not demonstrate actual causation themselves, but, if "plausible," they allow us to draw reasonable inferences from their results. If an experimental animal study demonstrates a mechanism for carcinogenicity, then it both makes it more plausible that the same will occur in the human model and it elucidates for us a possible mechanism of action for our evaluation.

In this sense, the district court and various *amici* have seemed to misconstrue what was gained from the animal experimentation in the Anderson studies.[25] *Amici curiae*, Bruce N. Ames, *et al.*, (at 18) support the decision of the trial court to reject the studies on the basis that: "'[t]he animal studies plaintiffs' experts relied upon were not indicative of a link between PCB exposure and Joiner's type of cancer because the conditions of the mice (huge doses, direct injection, use of initiator chemicals) were not similar to the nature of Joiner's exposure - his 'dose' was far smaller, and plaintiffs' experts have not identified an 'initiator'.[26] Those tests did not mimic human exposures." Obviously, it is easily recognized that there was hardly complete congruence between these experimental studies and Mr. Joiner's specific exposure. Given the practical

[25] Of course, there are other animal studies which have displayed the carcinogenic properties of PCBs. "Based on the observations of liver tumors in several studies of rats fed various commercial mixtures of PCBs in the diet and on suggestive evidence for carcinogenicity in humans (reviewed in (ATSDR) (1992)). *Draft Toxicological Profile for Polycholorinated Biphenyls*. (U.S. EPA) (1994). *Integrated Risk Information System (IRIS)*. The U.S. EPA has classified PCB mixtures as probable human carcinogens." Vater, et. al., *A Case Study of Cancer Data Set Combinations for PCBs*, in *Regulatory Toxicology and Pharmacology*, 22:2 (1995)

[26] Of course, this is not entirely accurate, as both Drs. Teitelbaum and Schecter assert that the "initiator" was cigarette smoke. Moreover, specifity, which seems to be required by these *amici*, is not an absolute for causal inference. Indeed, even for cigarette smoke, there is no *a priori* method to predict exactly which sites will be affected in a particular species, or perhaps even in an individual. Cigarettes will cause lung cancer in one person, bladder cancer in another, emphysema in a third, and leave another relatively unharmed.

requirements of animal experimentations it would be shocking if there was. The point of these studies seems to be missed. The fact that the studies did demonstrate an increase of lung tumors related to PCBs makes it more "plausible" that Mr. Joiner's lung cancer may be related to his PCB exposure. Whether it makes it more "probable" is hopefully, for the jury to decide.

J. The proper legal test of scientific conclusions is cross-examination

Ultimately, the determination of the proper methodology to use and the evidence to consider depends on the question which is being asked. Petitioners and the *amici* who support Petitioners seek the trial court to answer the following question: "Does the available toxicological and epidemiological data on PCBs more probably than not to a reasonable degree of medical certainty support the conclusion that PCBs cause small cell lung cancer so that that testimony may be presented to the jury?" They support the district court when it answered "no" to this question. Yet, for the district court to answer this question necessarily required that it make a factual determination regarding the evidence presented to it. We believe that the district court was really answering the wrong question. The question that it needed to address was: "Have Plaintiffs' experts used the proper methodology of their discipline to assess whether it is biologically *plausible* that Mr. Joiner's heavy exposure to a carcinogenic mixture of dielectric fluids during the course of his occupation contributed in some way to his early manifestation of lung cancer at the age of 37, even though his lung cancer was likely initiated by cigarette smoke?" To this question, on the basis of the very same epidemiological and toxicological evidence, the trial court should answer "yes" without having to evaluate the actual conclusions being drawn by the experts from the data they rely upon. As the D.C. Circuit has explained, "there is nothing in *Daubert* to suggest that judges become scientific experts, much less evaluators of the persuasiveness of an expert's conclusion." *Ambrosini v. Labarraque*, 101 F.3d 129, 134 (D.C. Cir. 1996), *cert. dismissed*, 117 S. Ct. 1572 (1997).

The further question of "whether it was more probable than not" is properly left to the jury to decide. And the proper technique to be utilized by the opponents of Plaintiff's position to challenge that conclusion is through cross-examination rather than motions to the court for relief.[27]

It is in this sense that *amici* herein agree with what this Court stated in *Daubert*:

> "[C]ross-examination, presentation of contrary evidence, and careful instruction on the burden of proof, rather than wholesale exclusion ... is the appropriate means by which evidence based on valid principles may be challenged.(at 5d) In this regard respondent seems to us to be overly pessimistic about the capabilities of the jury and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."(at 13 III.)

Most fundamentally, this Court has emphasized over and over again that the role of the jury may not be denigrated through the use of "trial on affidavits"[28] as was true in the within case before the district court. "Credibility determinations, the

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[27] Ultimately, we must look at why there is such a substantial controversy over the use of observational epidemiology and research toxicology, and why Petitioners and their *amici* urge that the district court review these studies in detail in the absence of clinical evaluation, occupational assessement, or a medical professional's differential diagnosis. In other words, why are Petitioners so ardently defending the right of the district court to prevent a jury from undertaking a review of the evidence presented. Is it that they feel that jurors are incompetent to make such evidentiary determinations? Is it that they are fearful that jurors might be duped by misinformation? Or is it that they are afraid that jurors will conclude that their products caused or contributed to the injuries alleged?

[28] This comment is especially relevant to the case below. As the district court admitted: "With one exception, neither party has provided the court with a copy of the studies cited in the briefs .... The court, for the most part, has had to rely on the excerpts from the studies that the parties have provided in their briefs." (63a n.27)

weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Indeed, it is the very "purpose of the jury...to sort out the true testimony from the false, the important matters from the unimportant matters, and, when called upon to do so, to give greater credence to one party's expert witnesses than another's. Such matters occur routinely in the American Judicial system, both civil and criminal." *Barefoot v. Estelle*, 463 U.S. 880, 902 (1983) (citation omitted). This Court has indicated that "the opportunity for cross-examination . . . is critical for ensuring the integrity of the fact-finding process. Cross-examination is "the principal means by which the believability of a witness and the truth of his testimony are tested." Indeed, cross-examination is the "'greatest legal engine ever invented for the discovery of truth.'" *Kentucky v. Stinger*, 482 U.S. 730, 736 (1987).

Petitioners underestimate the value of cross-examination in the context of a trial in which all of the evidence is before the trier of fact, whether it be judge or jury. Cross-examination often subjects a witness to scrutiny that is longer-lasting, more intense, and more extensive in the breadth of subjects examined than most any process occurring within the course of scientific debate. First, there are rarely time limits placed on cross-examination itself. Second, once on the witness stand, a witness may be obliged to endure a line-by-line scrutiny of any article or evidence the witness seeks to rely upon, being required to explain and defend every point. Third, the questions asked on cross-examination are not limited to the specific parameters of the paper or report that is the foundation of the expert's conclusion; instead, almost anything the expert has done, said, or written is open to examintion. For example, on cross-examination an expert witness can be subject to close questioning not only on the basis of the specific sources of his or her testimony, but can be impeached by anything he or she had said or written that is potentially inconsistent. His or her motives and credentials can be scrutinized in ways unimaginable to peer review editors, referees, conference organizers, and colleagues.

K. An expert's opinions should rely on the totality of the evidence reasonably considered

In conclusion, it is our view that the appellate court correctly concluded that: "[o]pinions of any kind are derived from individual pieces of evidence, each of which by itself might not be conclusive, but when viewed in their entirety are the building blocks of a perfectly reasonable conclusion." It is only through assessing the entirety of the evidence in the context of the injured worker's circumstances that an occupational medicine professional can properly evaluate causation. Data cannot be micro-managed; it must be reviewed in context and as a part of the totality of the evidence. Clearly, all forms of scientific data are subject to criticism on one ground or another, but that does not preclude valid judgments and determinations regarding causation if the various approaches are used with an understanding of their power and their limitations.[29] As stated by Sir Austin Bradford Hill:

> All scientific work is incomplete - whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time. ... [I]n passing from association to causation I believe in 'real life' we shall have to consider what flows from that decision. On scientific grounds we should do no such thing. The evidence is there to be judged on its merits and the judgment (in that sense) should be utterly independent of what hangs upon it - or who hangs because of it. But in another and more practical sense we may surely ask what is involved in our decision. In occupational medicine our object is usually to take action. If this be operative cause and that be

[29] Marcia Angell, an epidemiologist, in her *amicus brief* at 20 agrees with this in principle: "In reaching a decision about causation, the crucial consideration is the totality of evidence. (Citation omitted) Each study should be considered as part of a mosaic of information that taken together yields the answer to a scientific question."

deleterious effect, then we shall wish to intervene to abolish or reduce death or disease. (Bradford Hill at 295, 300 (1965)).

Amici submit that it is at the core of the very nature of our judicial system that we should do no less. Statutes of limitations and repose can place an equally severe time constraint on the ability of injured workers to gain redress. The need for proper medical intervention and the payment of medical bills will not wait. For ever more complete information or better, more particularized studies. If the evidence to be submitted is biologically plausible, if the methodology used in gathering that evidence is that used by practitioners in the field, then it should be submitted to the trier of fact. Otherwise, the newly framed and individualized *Daubert* approach portends severe inequity for injured claimants, as litigants with similar complaints may be subjected by different "gatekeeping" judges to substantially different evidentiary standards and validation processes.[30]

CONCLUSION

The judgment of the court of appeals should be affirmed.
Respectfully submitted.

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Counsel of Record

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[30] On this basis, this Court's review of the question presented is perhaps the most important question which could be addressed. In trial courts throughout the country motions based upon *Daubert*, if successful, invariably result in the granting of summary judgment. An appellate court reviewing a decision to exclude testimony is almost always reviewing the dismissal of the entire underlying claim. If this Court accepts the standard of review of these decisions as being an abuse of discretion or, worse, clearly erroneous, then it is issuing a salvo in favor of the trial judge rather than the jury as the true trier of fact. In very real terms, four separate judges have now reviewed the evidence presented by Drs. Teitelbaum and Schecter. Two found that it should be presented to the jury and two found that it shouldn't -- is there any better reason than this to state that the powers of the jury should not be usurped?

APPENDIX

The Oil, Chemical & Atomic Workers Intl. Union (OCAW) is an organization representing more than 90,000 men and women. Although OCAW was originally founded to represent oil and chemical workers, who still make up the majority of its membership, the union has grown to include workers in a wide range of energy, chemical, pharmaceutical, and allied industries.

Peter Orris received his MPH degree from Yale University in 1970 and his M.D. from Chicago Medical School in 1975. He is licensed to practice medicine in the state of Illinois and is a Diplomat of the American Board of Preventive Medicine in Occupational Medicine. Currently he has appointments as the medical director of Corporate Health Services, Northwest and as Professor of Preventive and Internal Medicine at Rush University College of Medicine. He also serves as Director of the Health Hazard Evaluation Program, University of Illinois School of Public Health and Illinois Department of Health; as the director of Research and Interdisciplinary Projects, Great Lakes Center for Occupational and Environmental Health and Safety, University of Illinois School of Public Health; and as an attending physician, Division of Occupational Medicine, Cook County Hospital. Among his many publications, he has written on the health effects of PCBs.

David Ozonoff received his M.D. degree from Cornell University Medical College in 1967 and his MPH from Johns Hopkins School of Hygiene and Public Health in 1968. In 1977 he became the first chair of Boston University's Department of Environmental Health in the new School of Public Health (a position he still holds). He currently holds the rank of Professor in the School of Public Health and Professor in the School of Medicine. His research work centers on health effects to communities of various kinds of toxic exposures, especially from hazardous waste sites; new approaches to understanding the results of small case-control studies; and the effects of exposure misclassification in environmental epidemiology. He has been principal or co-investigator of a number of major studies of waste sites, including the Silresim Superfund site and a large

case-control cancer study on Otis Air Force Base. He is currently the Principal Investigator of a Cooperative Agreement between Association of Schools of Public Health and ATSDR studying data needs for health assessment around DOE sites. He is also the Director of the Superfund Basic Research Center, a multidisciplinary effort to understand basic scientific problems connected with the Federal Superfund Program, funded by the National Institute of Environmental Health Sciences. In addition, he is the Medical Director of the Boston Environmental Hazards Center, a joint effort of the Department of Environmental Health and the Boston Veterans Administration Medical Center.

Janet S. Weiss received her M.D. in 1979 from Jefferson Medical College in Philadelphia, PA with honors in medicine and pathology. She is a Diplomate of the American Board of Medical Toxicology, a Diplomate of the American Board of Preventive Medicine in Occupational Medicine and Medical Toxicology, a Diplomate of the American Board of Pathology and a Diplomate of the American Board of Toxicology. She is an Assistant Clinical Professor of Medicine at the University of California, San Francisco's Department of Occupational and Environmental Medicine, and has consulted widely on issues of occupational medicine and medical toxicology for numerous governments, medical clinics, and pharmaceutical companies while maintaining a private practice in clinical toxicology. She has an extensive publication history in medical surveillance for occupational and environmental hazards.